Infection Control Measures Reduce Diarrhoeal and Acute Respiratory Infections in Child Care. A Randomised Controlled Trial

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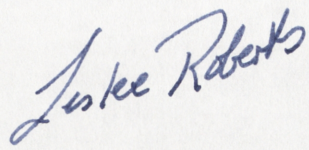
This thesis is entirely my own work conducted through the National Centre for Epidemiology and Population Health of The Australian National University.



Leslee Anne Roberts

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Abstract

Background

Children under five years of age who attend child care centres are at a higher risk of infectious diseases than their peers who stay at home.

Research question

Can training child care staff about infection control practices reduce the incidence of acute diarrhoeal and upper respiratory infections in children who attend child care centres? This question is addressed in two phases:

1. Can training child care staff enhance the recommended infection control behaviours of staff and children?
2. Can the recommended behaviours reduce episodes of acute respiratory and diarrhoeal infection in the children in this environment?

Study design

The design was a cluster randomised controlled trial in long-day care centres in the Australian Capital Territory (ACT). The research was conducted between March and November 1996. Child care staff were trained about infection control routines for carers and children. New procedures that were appropriate for the setting complemented the conventional infection control techniques. For example, I developed a novel routine for wiping children's noses: a small plastic "sandwich" bag covered the carer's hand when holding a tissue and the bag was aseptically inverted and discarded after the nose wipe. Furthermore, children's songs were developed to encourage children to wash their hands thoroughly, toy "sin bins" were established to store toys used throughout the day in preparation for washing, and computer paper was used as a disposable barrier on nappy change tables.

Outcome measures

An observer measured the extent to which infection control methods were implemented by staff and children. The impact of the intervention on child illness was measured through reports by parents in a structured telephone interview every two weeks.

Results

The performance of infection control practices was significantly better in intervention centres than in control centres over the trial period. There were 311 child years of surveillance for infection. Multivariable analysis showed that episodes of diarrhoea in intervention centres were 52 per cent lower than in control centres in children over 24 months of age. The greatest reduction, 66 per cent of episodes of illness, was seen when compliance with the intervention practices was high. This is the first reported controlled trial with multivariable analytic methods to show a reduction of diarrhoea in this age group in child care.

Multivariable analysis showed episodes of acute respiratory infection in children aged 24 months or under were 10 per cent less frequent in intervention centres. A dose response effect was present: as compliance with recommended practices improved, episodes of illness were less frequent. When compliance with children's handwashing was high, colds were reduced by 17 per cent. This is the first time that simple and practical infection control routines have been reported to significantly reduce the transmission of colds in a community setting.

Conclusion

Training child care workers enhanced infection control practices and reduced the incidence of acute diarrhoeal and upper respiratory infections. Implementing this training for child care workers across Australia has the potential to eliminate more than 300,000 episodes of illness each year in children in child care.

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Chapter 1 Introduction

Thesis overview

Children under five years of age who attend child care centres are at a higher risk from infectious diseases than their peers who stay at home. There are clear reasons why children in child care have a higher incidence of disease: they mix in a group setting, they have poor personal hygiene, they exhibit intimate contact with each other and their immunity to infections is not well developed. The research question that upholds this thesis is: can training about infection control practices for child care staff reduce the incidence of acute diarrhoeal and upper respiratory infections in children who attend child care centres?

In Chapter 2, I explore the evidence from the literature that children who attend child care centres suffer from more acute respiratory and diarrhoeal infections than their counterparts at home. I also review the evidence about how infections are transmitted, both in child care centres and other settings. This evidence provides a theoretical basis of the intervention: decreasing contamination of hands and fomites.

In Chapter 3, I outline the methods in this randomised controlled trial. The research question was addressed as a two step process: firstly, implementation of the practices; secondly, reduction in illness. My aim was to measure the outcome of both of these steps. To determine the extent to which staff in intervention and control centres implemented the practices taught in the training, an observer recorded practices in each centre for a period of three hours every six weeks. To measure the impact on child infections, parents reported illness in a structured telephone interview every two weeks. I measured potential confounders that may have affected a child's susceptibility to illness, according to a self-administered questionnaire by parents.

A cohort was successfully recruited and maintained for the trial, as described in Chapter 4. Chapter 5 presents the results of the observations from each centre, It examines to what extent the practices that were taught had been implemented, and whether these practices in intervention centres differed from those in control centres. Once it has been determined that the intervention succeeded in having the recommended practices implemented, the second phase of the question, whether these practices reduced illness, can be examined. Chapters 6 and 7 present the results of the impact of the intervention on episodes of acute diarrhoea and respiratory infections in children using multivariable analytic models.

For the purpose of the thesis, and because of the potential for the development of child care policy resulting from the impact on the two most common infections (acute respiratory and diarrhoeal infections), I present these results. The possibility that the intervention had broader effects beyond these illnesses is the subject of ongoing research on this dataset.

The thesis provides new contributions to knowledge about controlling diarrhoea and respiratory infection in children in child care. It also provides evidence about the mode of transmission of some respiratory infections in children in care. The trial established:

- the rate of respiratory and diarrhoeal illness in Australian children in child care that had not been previously documented;
- that training child care workers can enhance the performance of recommended infection control techniques;
- that the techniques can attain a large and significant reduction in episodes of diarrhoea in children over 24 months of age; and
- that the techniques can attain a significant reduction in episodes of cold in children 24 months or under, thereby providing evidence that direct transmission of colds is an important transmission route in young children in child care.

Candidate's background

I became interested in infections in children who attend child care while I was working towards a Masters in Applied Epidemiology. I had previously spent four years working in clinical microbiology and in 1991 I successfully completed a Part 1 Special Microbiology examination for the Royal Australian College of Pathologists. In clinical microbiology, I had responsibilities in infection control within the hospital. Because of this experience, I was surprised at the lack of infection control practices in child care centres when I enrolled my own child in a child care centre. I was also dismayed by the frequency with which children in care acquired illness. I was not alone in this concern. Child carers and parents alike worried about infections in the children and the children's contacts. With the aim of providing recommendations about how to reduce illness in child care, I coordinated a working group for the Communicable Diseases Standing Committee of the National Health and Medical Research Council. The terms of reference for the working group were to produce guidelines for infection control in child care. It was here that I became frustrated by the lack of published evidence to recommend any specific practices for reducing infections in child care, even though research documented convincingly that children in child care suffer from an excess of illness. The working group developed recommendations from theoretical principles of transmission of disease and the effect of infection control practices in other settings such as hospitals. The set of guidelines, *Staying Healthy in Child Care* was published and favourably received by the child care community. However, my frustration continued: how could we ask child care workers to institute major changes in their routines without the evidence that these changes reduce illness? Furthermore, some of the recommendations, were impractical to implement in child care. I designed this research trial to determine if infection control practices that were appropriate for child care were able to reduce infection.

Candidate's role in the trial

This trial is my own work. Contributions and other collaborators' contributions are summarised in Tables 1.1-1.4.

Table 1.1 Contribution to the intervention trial plan*

Task	Primary responsibility	Advice	Other significant input
Concept of research question	LR		
Study design	LR		
Obtaining of ethics committee approval	LR		
Application for grant	LR	LJ,MP,WS, RMD	
Choice of sample	LR	LJ	
Choice of sampling design	LR	LJ	

* Key to personnel follows Table 1.4

Table 1.2 Contribution to the pilot study*

Task	Primary responsibility	Advice	Other significant input
Recruitment of pilot centre	LR		
Observation of the practices in pilot centre	LR		
Training of staff in pilot centre	LR		
Recruitment of parents in pilot centre	LR		
Telephone interviews with parents in pilot centre	Datacol research		LR

* Key to personnel follows Table 1.4

Table 1.3 Contribution to the implementation of the trial*

Task	Primary responsibility	Advice	Other significant input
Recruitment of child care centres	LR		
Recruitment of parents	LR		child care staff
Letters to parents throughout trial	LR		
Development of calendar prompt for parent surveillance interview	LR		
Distribution of calendar prompts	LR		
Recruitment and training of observer	LR		
The intervention, development	LR		
The intervention, implemented training for child care workers	LR		
The intervention, reinforcement visits to intervention centres	LR		
The intervention, newsletters	LR		child care staff
Training of interviewers	Datacol Research		LR
Fortnightly telephone interviews	Datacol Research		
Follow up of parents not able to be interviewed	LR		

* Key to personnel follows Table 1.4

Table 1.4 Contribution to outcome measures*

Task	Primary responsibility	Advice	Other significant input
Development of fortnightly telephone interview questions	LR	LJ,MP,WS, RMD	
Development of children's questionnaire	LR	LJ,MP,WS, RMD	LJ
Development of centre director questionnaire	LR		
Development of observer record items	LR		
Distribution and collation of children's questionnaire	LR		SD
Development of database for children's questionnaire	LR		
Distribution and collection of director questionnaire	LR		SD
Entry and cleaning of surveillance data	Datacol Research		
Entry of children's questionnaire data	SD		LR
Cleaning of children's questionnaire data	LR		
Entry and cleaning of observation data	LR		
Analysis of observation data	LR	CM^{c}G,RA, WS,LJ	
Analysis of illness data	LR	CM^{c}G,RA, WS,LJ	

* Key to personnel

LR = Leslee Roberts

LJ = Louisa Jorm, Director, Epidemiology Branch, NSW Health

WS = Wayne Smith, Fellow, National Centre for Epidemiology and Population Health, ANU

MP = Mahomed Patel, Fellow, National Centre for Epidemiology and Population Health, ANU

RMD = Robert M Douglas, Director National Centre for Epidemiology and Population Health ANU

RA = Robyn Attewell, Instat Statistical Consultants

CM^cG = Charles McGilchrist, Professor of Biostatistics, National Centre for Epidemiology and Population Health, ANU

SD = Sharon Dale, trial centre observer

Chapter 2 Review of the Literature

Overview

Acute diarrhoea and respiratory infections are the most common illnesses in children in child care accounting for 46 per cent and 17 per cent respectively of absences from care[1]. These illnesses cause high morbidity as reports from numerous countries show that the incidence of infectious diseases in children who attend child care is higher than in children at home. Family members of children who attend child care are also at a significantly higher risk of acquiring infections. Knowledge about the occurrence of illness in children in child care, the method by which the infections are transmitted and the various child care practices that may affect transmission forms the foundation of an infection control intervention that may reduce infection in children who attend child care centres.

Acute diarrhoeal infection

Incidence in child care

The reported incidence of diarrhoea in children in child care varies from 0.17 to 5.12 per child year (Table 2.1)[2-10]. The range in these rates is due to the use of different definitions of diarrhoea and method of surveillance of illness. Two studies report a high incidence of five episodes per child year[3,4]. One of these studies used a very sensitive definition of diarrhoea and included in it children who had only one loose stool in 24 hours[3]. This may have included children with mild diarrhoea from causes other than infections. The second of the studies reported a high rate of diarrhoea during a specific peak diarrhoea period[4].

Table 2.1 Incidence of episodes of diarrhoea in children attending child care centres

	Year	Country	Age in months	Source of data	Rate per child year
Bartlett[4*]	1981	USA	< 36	carer	5.00
Black[5]	1981	USA	< 30	carer	4.00
Laborde[6]	1993	USA	< 24	parent	2.38
Lemp[7]	1984	USA	< 60	carer	0.68
Bartlett[8]	1985	USA	< 36	carer	1.02
Sullivan[2]	1984	USA	< 72	carer	0.44
Sullivan[2]	1984	USA	< 36	carer	1.24
Bell[9]	1989	USA	< 36	physician	0.17
Collet[10†]	1994	France	< 36	carer & parent	1.09
Kotch [3] all diarrhoea	1994	USA	< 24	parent	5.12
Kotch [3] severe diarrhoea	1994	USA	< 24	parent	1.11

* Surveillance of 10 week period
† Surveillance of 8 month period

At the other extreme, low rates of less than one episode per child year have been reported in these studies. The rates reported by Lemp and Sullivan are low because they encompass a wider age range of children and, as noted below, older children have a lower incidence of diarrhoea. Both these and the lower of the rates reported by Bartlett could also be expected to be low because they relied on reports of illness by child care staff only on weekdays[2,7,8]. Similarly the very low rate reported by Bell may reflect an ascertainment bias because of a specific case definition; a case of diarrhoea was included only if diarrhoea was diagnosed by a physician[9]. In a similar limitation, the case definition used by Kotch for severe diarrhoea was very specific, resulting in a low rate, and one that is not comparable to others[3]. The work by Laborde et al presented an incidence in the mid-range of the extremes, and probably a more realistic picture of the incidence[6]. Their surveillance consisted of interviews with parents, but each in a reasonable time to recall events, every two weeks.

The mean rate of diarrhoea is used for sample size calculation in Chapter 3 Methods. From Table 2.1 the mean rate is 2.0 episodes per child year; however, this includes potentially spuriously high and low rates. The mean rate excluding the three highest and the two lowest rates in Table 2.1, and the one used for sample size estimation, is 1.4 per child year.

Relevance to Australia

The only reported incidence of diarrhoea in Australian child care centres is from a study of diarrhoea caused by rotavirus. According to this study, there were 37 episodes of rotavirus diarrhoea in 2,249 child weeks, representing an incidence of 0.86 per child year[11]. This is much higher than the rate for rotavirus reported in the USA in 1985 by Bartlett of 0.15 episodes per child year[8].

Incidence by age

The rate of diarrhoea in children in care decreases with age. Between 11 and 17 times the rate of diarrhoea, are reported in children three years of age and under, compared with those aged four and five years (Table 2.2)[2,7]. There are plausible biological reasons for older children to have lower rates of disease. Children aged

four and five years are independent with their toilet use, have had time to develop their immunity to infection and are less likely to be in contact with other children in nappies. However, the method of surveillance of diarrhoea by Lemp and Sullivan may have falsely elevated the difference. In both studies the researchers interviewed centre staff and directors to determine episodes of diarrhoea. Diarrhoea in older toilet trained children would have been less likely to be detected by the staff than diarrhoea in children in nappies. Despite this, the lower rate in four and five year olds is likely to be a real finding, even if it is not as large as 17 times lower than younger children. The lower susceptibility of older children in outbreak situations was shown by Pickering; high attack rates in the young, 76 per cent susceptibility in children under 12 months of age decreased with each year to 23 per cent in children five years of age[12].

Table 2.2 Ratio of rate of acute diarrhoea in younger children compared with older children

Author	Year	Young age group in months	Rate per child year	Older age group in months	Rate per child year	Ratio (young:older)
Black[5]*	1981	<=17	4.21	18-29	3.50	1.2
Bartlett[8]	1985	<=12	1.12	13-36	0.98	1.1
Kotch[3†]	1994	<=23	1.33	24-36	0.77	1.6
Sullivan[2]	1984	<=35	1.24	36-60	0.07	17.0
Lemp[7]	1984	<=35	2.90	36-60	0.26	11.0
Laborde[6‡]	1993	<=24	2.28	25-36	1.25	1.8

* Children in control group in baseline and study period
† Severe diarrhoea in control group
‡ From data provided in the publication

Children in child care have more acute diarrhoea episodes than children at home

From the National Health Interview Survey in the United States, Alexander reported a higher risk of acute gastrointestinal illness in children who attended child care than their counterparts at home. From multivariable analyses, Alexander found a 3.5 times increased risk of diarrhoea from child care

attendance, but only in younger children under three years of age who regularly attended centres[13]. In this same age group, Reves reported an increased risk in a case control study of children enrolled in a health clinic in the USA. The risk for acute diarrhoea in children attending child care centres was 2.4 times that of children at home[14].

Comparative incidence

Cohort studies comparing infection in children in care at the same time as children at home have also shown a higher risk in centre attendees[4,10]. Bartlett studied diarrhoeal illness in children under three years of age in child care centres, family day care homes and 102 households over a period of 10 weeks[4]. The period of surveillance was chosen because it was a peak period for diarrhoeal illness. The incidence was significantly higher in the children who attended child care centres than children at home, being 5.04 and 2.76 per child year respectively. At least during peak periods, children in care had more illness than their peers at home. Collet, in another direct comparison, this time in France, found the incidence of gastroenteritis to be 1.09 per child year in children in child care centres, 18 times higher than the rate of 0.06 per child year in children who did not attend care[10]. In this work, gastroenteritis was defined as the acute occurrence of a new symptom lasting for at least 24 hours and resulting in specific treatment. The requirement that illness be counted only if it included treatment may have biased the study towards higher rates in children in child care. Parents of children in care may have been more likely to seek treatment earlier than parents at home because of their need to attend work.

Three of these studies therefore reported a two to three times increased risk of diarrhoea for younger children in child care than for their peers at home[4,13,14] Only one study has reported that the occurrence of diarrhoea in child care centres is lower than in the children's own home. Bell reported the mean number of diarrhoeal infections was 0.17 per child year in child care centres compared with 0.26 per child year at home. The much lower rates reported here can be partly explained by the inherent measurement bias; an episode was included only if diagnosed gastroenteritis by a doctor. Self-limiting episodes of gastroenteritis

may not have resulted in consultation with a physician. Nonetheless the results are not consistent with others and are surprising because children who attend child care may be more likely to attend a doctor because of the impact of their illness on their parents work[9].

Risk of infection is higher in children who are new to care

Children who are newly enrolled in a centre may experience their first exposure to enteropathogens. Staat reported that children in their first four weeks in child care had a 1.6 times more significant risk of diarrhoea than in subsequent weeks[15]. Bartlett showed that children who had been enrolled in centres for less than six months were significantly more likely to be ill during a centre outbreak of diarrhoea[8]. Of course the duration a child has been enrolled is likely to be shorter for younger children, who are more susceptible to illness, but this association maintained its significance when stratified by age group. Reves also suggested that the risk of diarrhoea was higher when children were new to child care in a case control study[14]. Although of borderline statistical significance, the risk of diarrhoea in the first month of enrolment was 1.6 times higher than for children who had been attending child care for one month or longer (95% CI 0.9 - 2.8).

Children who have already attended other centres do not appear protected from the increased risk when they start in a new centre. Staat showed the rate of diarrhoea in children with a history of previous child care attendance was 3.4 per child year, not significantly different from 2.8 per child year among children who had not previously attended a child care centre. Both groups had a significantly higher incidence of diarrhoea in their first four weeks than in later weeks[15].

Population attributable risk

The question of what proportion of diarrhoea in children in the community can be attributed to attendance at child care has not been widely studied. Recently, Louhiala reported that the proportion of episodes of diarrhoea attributable to child care centres was 49 per cent in children under one year of age, but the 95 per cent confidence interval around this estimate was wide being from 18 per

cent to 91 per cent[16]. The population attributable risk for all children aged one to seven years was 17 per cent (95% CI, 7-29%). This is a similar estimate to that reported by Reves: 19 per cent of episodes of diarrhoea in children in a health maintenance organisation clinic were attributable to child care attendance[14]. Forty per cent of children enrolled at the clinic attended child care.

Secondary infections in families

The impact of diarrhoeal infection in children in child care is not limited only to child care attendees. Weissman showed that preschool children played a major role in introducing illness into their family in community outbreaks of *Shigella sonnei*[17]. Children who attended child care centres were significantly more likely than children who were at home to be the initial case and major cause of spread within their family. The secondary attack rate in households with a preschool age child was 36 per cent, significantly greater than the rate of 13 per cent in households without an ill child of preschool age ($p<0.01$).

The attack rate in family members can be high (Table 2.3). Overall Pickering et al found an 11 per cent attack rate in family members when children from child care centres had gastroenteritis of any cause[12]. Pickering found no correlation between secondary attack rate and family size or proportion of adults in the home. Transmission of diarrhoea from children in care to their families has been reported in Australia; Ferguson reported secondary cases from outbreaks in 88 family members with an attack rate of nine per cent with a range of one to 15 per cent [18]. Most of the outbreaks were of unknown aetiology. Ferson in Australia reported cases of rotavirus in 38 family members of 44 children but did not provide the total denominator of family members to calculate the attack rate[11]. Rotavirus is recognised as spreading readily amongst family members[19].

Table 2.3 Secondary attack rates of diarrhoea by organism within family members of children with diarrhoea in child care

Author	Year	Organism	Secondary attack rate per cent
Weissman[17]	1974	*Shigella*	62
Black[20]	1977	*Giardia*	25
Pickering[12]	1981	*Shigella*	26
		Giardia	17
		rotavirus	15
Tangerman[21]	1991	*Cryptosporidium*	31
Ferguson[18]	1995	*Mixed*	9

Outbreaks

Outbreaks of acute diarrhoea are commonly reported from child care centres. Some centres experience three outbreaks of gastroenteritis in a year, while others may report none[8]. Pickering identified 15 outbreaks of diarrhoea in 20 child care centres over 19 months[12]. The attack rates in children in the centres ranged from 17 per cent for an outbreak of *Giardia* to 71 per cent for outbreaks of rotavirus. The mean duration of each outbreak was 2.4 weeks, with a range of one to six weeks. Bartlett identified a similar number of outbreaks in his two year study being 18 outbreaks in 22 child care centres[8]. In Australia, Jorm identified 60 outbreaks of diarrhoea in 92 centres over 12 months[22]. This is a similar rate to that reported by the investigators in the USA (Table 2.4). The mean duration of the outbreaks was also similar at 2.1 weeks. A lower rate was subsequently detected in a study in the same area by Ferguson and Jorm, and the mean duration was slightly shorter of 1.6 weeks[18].

Table 2.4 Rate of outbreaks of diarrhoea per child care centre per year

Author	Year	Country	Outbreaks	Number of centres	Period (months)	Rate per centre year
Pickering [12]	1981	USA	15	20	19	0.47
Bartlett[8]	1985	USA	18	22	15	0.66
Jorm[22]	1994	Australia	60	92	12	0.65
Ferguson[18]	1995	Australia	9	35	11	0.28

Agents of diarrhoea in child care

In 1985, Bartlett found that the seasonal distributions and causes of acute diarrhoea were similar in children who attended child care centres and children who were at home[4]. *Giardia*, rotavirus and *Camplyobacter* were the most common organisms identified, although *Salmonella* and *Shigella* also caused sporadic cases[8]. The pathogens that caused diarrhoea differed by children's age. Bartlett found *Giardia* infection was more frequent among children in their second and third year and that rotavirus infection was more frequent in children in their first year[8]. Bartlett also found that multiple pathogens were detected in 11 per cent of outbreaks, a finding also reported by others[8,12,23].

Rotavirus is the most common viral enteropathogen isolated from children with diarrhoea in child care accounting for 10 per cent of all diarrhoea[24]. However, other viruses have been implicated in outbreaks of diarrhoea in centres. From the stored stool samples collected by Bartlett in 1985, two later studies have evaluated the role of other viruses in child care outbreaks. Matson in 1989 examined the samples for caliciviruses, and found these to be present in three per cent of diarrhoeal stool specimens, that is, it is half as common as rotavirus[25]. Human calicivirus was not detected in any stools of 86 asymptomatic contacts. As with rotavirus, human calicivirus associated diarrhoea was more frequent in young infants than in older infants. Calicivirus has been reported as causing an outbreak of gastroenteritis in a child care centre in Australia[26].

Using the same stools collected in the work by Bartlett, Lew reported that astrovirus was an important cause of diarrhoea as it was present in a significantly greater percentage of children with diarrhoea, four per cent compared to less than one per cent for controls. Astrovirus may have accounted for seven per cent of Bartlett's outbreaks, although again half of these were in the presence of another pathogen. Astrovirus has also been documented to have caused outbreaks in a prospective study of child care centres and is recognised as the responsible agent

in two to eight per cent of diarrhoea episodes in children presenting to hospital[27,28].

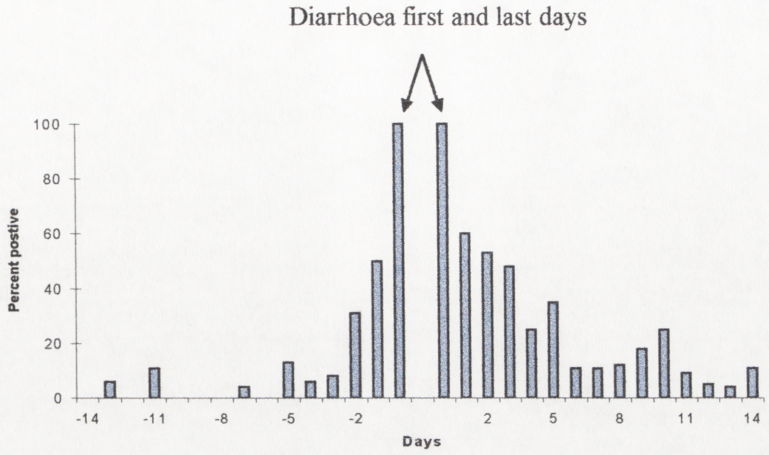
In contrast, Lew found that adenovirus was probably not causing disease in children in child care, for it was present in two per cent of both cases and controls[29]. In other work, Van found adenovirus in eight per cent of all diarrhoea outbreaks over a six year period[30]. However, in almost half of these samples, other pathogens were also detected. The role of enteric adenoviruses in outbreaks in child care centres is not yet clear.

Duration of excretion

After an episode of acute diarrhoea, children may excrete enteropathogens for weeks. Cryptosporidium shedding has been reported for a mean duration of 16.5 days after the onset of illness[21]. Calicivirus is excreted in the stools of symptomatic children for up to nine days, and astrovirus RNA can be detected up to 35 days after illness[25-27].

Pickering provided considerable evidence about asymptomatic excretion of rotavirus and showed that excretion continued until two weeks after recovery in some children. However, excretion also occurred in 50 per cent of children the day before they became unwell, and in 30 per cent of children two days before they became unwell (Figure 2.1)[31]. Children infected with rotavirus often excrete more than 10^9 particles per gram of faeces[32]. The evidence about prolonged and pre-illness secretion of rotavirus, along with high numbers of virus particles in stool, shows the opportunity for contamination of the environment by children, including by those children who appear healthy. Rotavirus contamination of the child care environment has been well documented and in experimental situations it can survive in faeces for up to 10 days on surfaces and is able to cause gastroenteritis by ingestion even after the organism has dried[33-36].

Figure 2.1 Per cent of children excreting rotavirus in their stool before the onset of diarrhoea and after the cessation of diarrhoea from Pickering et al[31]



Asymptomatic excretion of pathogens

Healthy children who attend child care may also excrete enteropathogens in their stool. Asymptomatic carriage has been well described in children in child care centres for a wide range of organisms including *Giardia, Cryptosporidium*, rotavirus, adenovirus, calicivirus and astrovirus[21,30,33,37-39]. Bartlett reported that in groups where a pathogen was detected in one child, asymptomatic carriage was present in 14 per cent of children in the same care room[8]. In four child care centres in Mexico, an enteropathogen was detected in 40 per cent of asymptomatic children during routine surveillance[38]. The presence of enteropathogens in children's stools when the children show no sign of illness, and either remain asymptomatic or are before or after illness, denotes a risk of transmission of these pathogens to susceptible children. If faeces are not disposed of aseptically, or if hands in contact with faeces are not adequately washed, organisms that are able to cause disease may spread to others.

Table 2.5 Prevalence of asymptomatic excretion of enteropathogens in children and adults in child care centres

Author	During outbreak	Organism	Children n (%)	Adults n (%)
Tangermann[21]	Yes	*Cryptosporidium*	9/40 (23)	3/23 (13)
Barrón-Romero[38]	No	*Giardia*	40/564 (7)	7/302 (2)
Barrón-Romero[38]	No	rotavirus	169/564 (30)	62/302(21)
Keswick[37]	No	rotavirus	38/445 (12)	not done
Grohman[26]	Yes	calicivirus	4/73 (5)	3/22 (4)
Barrón-Romero[38]	No	any enteropathogen	230/564 (41)	114/302 (38)
Kim[40]	Yes	*Clostridium difficile*	7/44(16)	not done

Reducing the spread of diarrhoeal infections

Controlling the spread during outbreaks

Success in controlling the spread of pathogens during outbreaks in child care centres has been limited. Grohmann found that during an outbreak extensive efforts to control the spread of calicivirus were unsuccessful[26]. Grohmann's control measures were aimed at improved handwashing, prevention of food contamination, and exclusion of ill children and staff for 24 hours after their last episode of diarrhoea. Although Grohmann mentioned that shared articles such as toys and books were eliminated, it is hard to envisage how the child care centre would have continued to operate without toys. Grohmann did not comment about whether toys were cleaned in their intervention. Similarly, Steketee et al were unable to prevent recurrent outbreaks of Giardia in one large child care centre despite facilitating the cleaning of the centre along with improving personal hygiene[41]. However, they noted that they made no change to the centre's policy that toys were washed only once a month. It seems surprising that they targeted environmental cleaning but did not address the fomites that are the main focus of a child's day, namely toys.

The effectiveness of excluding children with diarrhoea in order to control the spread may be limited. Effectiveness of exclusion has not been, and is never likely to be, scientifically tested. It would be unethical to randomise children to a control group of non exclusion where they may be at risk of serious dehydration. Furthermore, not excluding children with diarrhoea would change the role of carer into nurse, an impractical arrangement in a care group of children. Although children with diarrhoea pose a risk of contaminating the environment with leakage of liquid stool, we know that they are not the only children excreting organisms. Similarly they may have contaminated the environment before the onset of their illness and exclusion. Management of all children's stools, not only those stools that are liquid, appears crucial in outbreak control. However, child care workers place a great emphasis on exclusion as a control measure and express reassurance that they have controlled spread when an unwell child has left their care. Grohman's exclusion intervention was particularly problematical. The nursery closed for 11 days but reopened because parents had begun enrolling their children in other child care centres. Clearly children excluded from one centre because of a diarrhoeal outbreak would pose a risk of introducing this organism to another centre.

Cohorting of children with the same illness has been successful, but only with children with *Shigella* or *Salmonella* infection, whose diarrhoea had ceased and who were receiving treatment[42,43]. This approach to diarrhoea control appears restricted to children who are receiving treatment to eradicate the organism, thereby limiting the use to bacterial and *Giardia* infections. Even then, with the high frequency of children excreting more than one pathogen, children in a "diarrhoea cohort" for a particular organism, may be at risk of acquiring a new pathogen. The role for cohorting appears limited to only a few circumstances.

The inability to control outbreaks of diarrhoea with hygiene interventions became of particular concern with the transmission of *Escherichia coli* 0157:H7 infection that caused Haemolytic Uraemic Syndrome (HUS) in three unrelated children in one child care centre[44]. Attendance at a large child care centre of more than 50 children had previously been reported as a risk factor for HUS[45]. Twenty-three per cent of children attending the centre had either a positive culture, bloody

diarrhoea, or HUS. Transmission occurred in all three age segregated rooms. The investigators managed the outbreak by exclusion, refusing to admit children until they had two clear stool cultures. They made efforts to discourage the parents from enrolling their child in another centre during the exclusion period. This was a labour intensive intervention that disrupted the lives of affected parents and children, but there were no further cases from the centre. In this instance, exclusion of the child was accompanied by antimicrobial treatment to eradicate carriage, and by testing of the efficacy of that treatment.

Another emerging organism in child care outbreaks is *Clostridium difficile* and it's toxin[40]. With a high frequency of use and reexposure to antibiotics by children in child care there is the potential for development of antibiotic associated/ pseudomembranous colitis. The presence of *Clostridium difficile* and it's toxin in child care may be underestimated because of lack of testing. In an outbreak situation 62 per cent of symptomatic and 16 per cent of asymptomatic children excreted *C difficile*[40]. Control strategies for spread of diarrhoea in outbreaks are needed.

Each of the investigators that managed an outbreak targeted handwashing within the centre. Physical removal of organisms from hands by the abrasive process of is effective[46-49]. Sprunt tested the ability of handwashing agents in similar situations to that of child care workers[46]. When nurses changed a baby's nappy that contained stool or patted the baby's buttocks, they acquired coliforms on their hands in 90 per cent of experiments. These coliforms were reduced by 90 per cent with any of the handwashing agents; water, soap, hexachlorophene, povidone iodine and ethyl alcohol.

Washing of hands with water and soap removes 90 to 100 per cent of recently acquired organisms. However, most tests of the effectiveness of handwashing have used a duration of washing of 15 seconds or more:

- washing hands with soap and water for a combined time of 25 seconds removed > 98 per cent of *Klebsiella* species[47];

- washing hands for 30 seconds with soap and running water removed 99 per cent of *Staphylococcus aureus* contaminating hands[48]; and
- washing hands with soap and running water for 15 seconds removed 10^6 colony forming units of *Salmonella anatum* from fingertips[49].

The use of disinfectants or medicated soaps for handwashing does not improve the numbers of organisms removed[46,47]. Indeed some studies show that water alone without the use of soap removes almost as many organisms as water alone[46,47]. However, what has not been reported is whether the use of soap influences the duration of the handwash. In an emergency department, the average duration of a handwash using soap and water was 9.5 seconds with a range of one to 48 seconds[50]. Are adults or children likely to wash their hands consistently for 15 to 20 seconds without the use of a lubricating agent such as soap?

Child care environment and practices associated with diarrhoea

Factors such as group size and mixing of children of different age groups have been shown to contribute to the spread of diarrhoea in child care centres. In Australia, Jorm showed that centres which provided care for 50 or more children were significantly more likely to report outbreaks of diarrhoea than centres with enrolments of less than 24 children[22]. Also, directors of centres that commenced operation in the previous two years reported more outbreaks of diarrhoea than longer established centres. Pickering reported that in nine outbreaks, spread of diarrhoea across more than one age group occurred only in centers where children of all ages mixed together[12].

Other characteristics of centres that have been associated with higher rates of disease include: the presence of young non-toilet trained children, staff duties and whether or not the centre's operation was for profit[2]. Lemp reported that having non-toilet trained children less than two years of age in care increased the incidence of diarrhoea by a factor 3.55 compared with centres that did not have children under two years of age in care[7]. There were also significant correlations between the incidence of diarrhoea and nappy and food duties of staff. The

relative risk of diarrhoea was 3.28 (95 % CI 2.81-2.82) when staff members combined the functions of preparing meals, serving food and changing nappies compared with centres where staff did not combine these functions. The risk remained elevated at 1.74 (95 % CI 1.41-2.14) when staff served, but did not prepare, food and changed nappies[7].

Poor hygiene standards are correlated with outbreaks of diarrhoea[8]. Bartlett showed outbreaks correlated with poor handwashing including lack of handwashing by children and lack of staff handwashing after nappy changes, after using a toilet and before preparing food. Low standards of food management were also correlated, including child participation in food serving, sharing of food, and eating in areas used for other activities.

Environmental contamination

Enteropathogens are spread by the faecal-oral route, so faecally contaminated fomites and hands in child care enable the transmission of organisms to mouths. Van showed the occurrence of diarrhoea in child care was significantly associated with contamination of staff and children's hands with coliforms[51]. Laborde reported that classrooms with any hand contamination or contamination on moist sites had a significant two fold increased rate of diarrhoea compared with rooms without contamination[6].

There is a clear link between faecal organisms in the environment and outbreaks of diarrhoea in centres. Ekanem showed that during outbreaks, faecal coliforms were significantly more frequently isolated from hands and objects in rooms[52]. Interestingly, the levels of contamination in toilet areas remained almost the same during outbreak periods as during normal periods. In contrast, contamination of toys rose from less than 10 per cent at non-outbreak periods to 40 per cent during an outbreak. However, the presence of coliforms may not always be a reliable indicator of enteropathogen contamination of the environment. Wilde found that the presence of rotavirus in environmental samples was not correlated with the presence of coliforms, but environmental contamination with rotavirus occurred during rotavirus outbreaks[33]. Wilde reported that in centres with rotavirus

outbreaks, 39 per cent of toy balls had detectable rotavirus as did 21 per cent of environmental surfaces. This compared with only five per cent and two per cent of the respective fomites in control centres[33].

In this setting, small fomites such as toys are directly put into children's mouths. In Laborde's work, faecal contamination was most often present on hands and sinks, but of the dry surfaces that were tested, the highest level of coliforms were found on toys with at least 10^3 colony forming units. Child hand coliform levels were correlated with toys (rho= 0.45 p = 0.006) and tables (rho = 0.49 p = 0.003)[6]. Van et al also found that faecal coliform contamination of children's hands and objects in child care rooms was common[51]. Between 12 and 52 per cent of toy balls placed in the rooms were contaminated with faecal coliform bacilli. Van highlighted the frequency of children's contact with toys. During one hour observation periods, six study balls in a room were handled by between two and eight children.

Toys and other parts of the environment can be contaminated with organisms from faeces by: direct faecal leakage from nappies, episodes of faecal incontinence in children who are able to use a toilet, or hands that have been contaminated. Direct faecal leakage probably plays an important role in environmental contamination and is difficult to control in children who have liquid diarrhoea. Kubiak et al studied the role of types of nappy and overclothes on faecal containment. They used simulated stool that contained a fluorescent dye inside different types of nappy. The stool had the measured viscosity of a moderately loose infant stool[53]. With all types of nappies, disposable or cloth with vinyl pants, the spread of faeces occurred past the edge of the nappy. However, disposable nappies were significantly better at containment of the artificial faeces. Van reported that environmental contamination with coliforms was less when disposable nappies were worn[54]. Contamination was also less when clothing was worn over nappies. This is consistent with Kubiak's finding that stools leak beyond the edge of the nappy. Kubiak's and Van's work on faecal containment in nappies and environmental contamination highlight the importance of ensuring that stools are contained and more than one barrier

prevents spread to the environment. Clothes are not always worn over children's nappies and plastic pants in Australian child care, particularly on hot days and when the children are soon to be put to bed. Unfortunately bed or rest time frequently follows meal times, and children can be sitting at tables or in high chairs wearing only nappies and plastic pants.

Rooms where children wear nappies and children are mobile, such as toddler rooms, have higher levels of contamination and therefore risk of spread of diarrhoea than infant rooms. Van reported that toy balls, hands and environmental surfaces were all significantly more contaminated in rooms with toddlers compared with infants[51]. Similarly contamination was more frequent on the hands of children than on the hands of staff in toddler rooms, but not in nursery rooms[6].

Disinfectants

Readily available disinfectants for use in child care include phenolic compounds, quaternary ammonium compounds and bleach. The requirements for disinfectants in child care are that they need to be active against the target organisms, to remain effective in the conditions that they are used, to be compatible with the materials to be disinfected, and to be harmless for the workers and children[55]. Although details of disinfectants are highlighted for child care workers in the manual *Staying Healthy in Child Care*, they may still not be well understood[56]. Limitations such as the reactive nature of bleach with organic matter, resulting in it only being effective on surfaces that have already been cleaned, may make it inappropriately used[55]. Experimentally, bleach in the form of Milton antibacterial solution diluted one in 80 as recommended for sterilisation of babies bottles had little effect on rotavirus even with two hours exposure time[57].

The time available for the disinfecting process is a limiting factor in child care. Surface disinfectants at suitable concentration will frequently need to be in contact with the organism for around 10 minutes. A spray of Lysol (phenylphenol and ethanol), left to dry for 10 minutes as instructed by the manufacturer, prevented transmission of rotavirus from fomites to volunteers[36]. There is not a

10 minute break between uses of a toilet or a change mat by children in child care.

Reliance on the use of a disinfectant that may only act as a detergent can create further contamination. When quaternary ammonium compounds and phenolic compounds were used on surfaces contaminated with rhinovirus, there was a 10 fold higher amount of virus recovered from fingerpads that had been in contact with the treated surface compared with non-treated surfaces[58]. It appeared that the disinfectants were ineffective germicides and that they facilitated the spread of the virus along a surface. At least when surfaces are washed with detergent and water, the individual is aware that they are flushing away organisms and are not deluded into believing that they have killed organisms.

The use of disinfectants on hands also carries the same limitation of exposure time. For example, alcohol in 95 per cent concentration is effective in inactivation of rotavirus; however, concentrations lower than this are not effective within the time of a normal handwash[57]. Another difficulty is that high concentrations of alcohol have a drying effect on the hands. Even other disinfectants commonly used for handwashing (Betadine, Hexol, Hibiclens and Hibitane in alcohol) were not effective at inactivating rotavirus within the time of a handwash. Physical removal of organisms by abrasion and washing seems more useful in child care routines; however, disinfectants may have a role at specific steps in a days routine if used correctly.

Four intervention studies

Four studies have prospectively assessed the impact of infection control training for staff on the occurrence of episodes of diarrhoea in children[3,5,59,60]. Their success has ranged from no impact to impressive results, however, only one study has been methodologically well performed. In the limited, but hallmark, study by Black et al in 1979, diarrhoea in child care centres was reduced by 50 per cent when handwashing was improved and "rigorously monitored"[5]. However, it is not possible to know if the rate of diarrhoea was falsely reported in this study, as

the care givers who instituted rigorous washing were also the ones who reported episodes of diarrhoea.

Bartlett et al in 1988 reported that staff training did not reduce diarrhoea[59]. The training was conducted in the third year of a longitudinal study, but there was no measure of whether the training improved hygiene practices. The rate of diarrhoea was higher in the first study year than in the second two years of surveillance. In the first phase of the study, the authors found adherence to hygiene was associated with a lower risk of diarrhoea. It is not clear if these results were available to the centre staff before the hygiene training intervention commenced. Knowledge of these results may have resulted in changed behaviour. Similarly, surveillance of illness in child care is an intervention itself, and it may be that this reduced infection. Supporting the argument that the investigators had intervened by surveillance in the first two years was the finding that in all 21 study centres (10 intervention and 11 control) the risk of diarrhoea was significantly lower than in the four child care centres that were not in the earlier surveillance study.

An intervention study by Butz et al used a setting, not child care centres but family day care homes, that involved care of six or fewer children in the carer's own home[60]. The risk of exposure to diarrhoeal disease could be smaller in these children than those in centres. However, the implementation of good hygiene practices in a domestic setting may have been more difficult than in centres. For example, a bench for changing nappies was not likely to be juxtaposed to a sink for handwashing. The intervention targeted handwashing along with use of gloves, and involved an alcohol-based hand rinse and a disposable nappy change mat. The work was limited methodologically; again there was a potential measurement bias because the carers who received the intervention training were the source of the surveillance data. Butz et al reported only symptom days and did not estimate episodes of illness, one episode could therefore have contributed significantly to the number of ill days, and they did not adjust for any confounding effects on their results. Their crude results were that the number of days that children had diarrhoea was reduced by 29 per cent and that the number of days that children had vomiting was reduced by 67 per cent.

In all these studies, the care givers who received training were also the source of information about child illness. This is an important potential bias. None of the studies controlled for potential confounders such as age, breast feeding or being new to child care. The only trial to address these issues was that by Kotch et al. In a multivariable model that adjusted for the age of the children, ethnicity, quality of home and centre characteristics, Kotch et al found almost a 50 per cent reduction in episodes of severe diarrhoea. However, when stratified by age, the impact of the intervention was only seen in children under 24 months of age. Episodes of diarrhoea that were not classified as severe were also lower in intervention centres, but this was not a statistically significant decrease. Because Kotch et al only reduced diarrhoea in younger children, they concluded that the intervention may have had less impact on child to child spread than on worker to child transmission[3].

None of these intervention studies comprehensively evaluated whether its intervention translated into changed behaviour. Bartlett performed no measure of behaviour, Black noted that the trainers observed that practices were "rigorously performed" and Butz measured the use only of disposable items[5,59,60]. Kotch used the same staff who conducted the training to record observations of behaviours but only reported on the behaviour of child care staff with handwashing[3]. These trainers may have been biased in their observations. Understanding how well the intervention was implemented is crucial in understanding if the intervention was effective. A failed intervention may represent either a failure of the practices to reduce transmission or a failure of the practices to be put into place.

Acute respiratory infection

Incidence in child care

The published rates of respiratory illness in children in care vary widely from a low of 3.9 per child year up to 15.7 per child year[3,10,61-64]. This disparity in rates can be explained by different case definitions, methods of surveillance of illness and the age group of children that were studied. What is consistent throughout the research is that older children in care have a lower incidence of respiratory illness than younger children in care.

Reports for all children under five years of age in child care show that the children acquire approximately seven upper respiratory infections per year (Table 2.6). Respiratory tract infections in children in care have been studied for over 24 years in one centre in the USA, the Frank Porter Graham Centre (FPG). In 1969, the incidence of acute respiratory infection at that centre was reported to be over eight per child year. In more recent years, the incidence has been reported to be closer to six per child year.

Table 2.6 Incidence of respiratory illness per child year in children aged 0 - 5 years in child care centres

Author	Country	Dates of Surveillance	Surveillance period	Rate per child year
Loda[61]	USA*	Sept 1966 - Dec 1969	3 years, 3 months	8.4
Denny[62]	USA*	Sept 1966 - Dec 1982	16 years, 3 months	6.5
Schwartz[63]	USA*	Sept 1966 - Aug1990	24 years	6.1
Strangert[64]	Sweden	Sept 1973 - April 1974	8 months	6.5

*Frank Porter Graham Centre

Incidence by age

The rate of respiratory infection is higher in younger children in care and decreases with age (Table 2.7). In the work from the FPG centre, Schwartz et al and Loda et al showed that the rate decreased with each year of life with the highest rates in children under one year of age. Although the length of surveillance from this work makes the results compelling, there are no published details about what defined a respiratory illness nor about what classed each illness as a new episode of illness.

Table 2.7 Incidence of acute respiratory illness, Frank Porter Graham Centre USA by age group

Age	Loda [61] Sept 1 1966 - Dec 1969	Schwartz [63] Sept 1 1966 - Aug 31 1990
<1	9.6	8.9
1	8.6	7.8
2	8.1	6.0
3	7.2	4.4
4	7.6	3.3
5	6.7	Not reported

A clear case definition was used in a longitudinal study of children in their first three years of life by Wald et al[65]. A simple upper respiratory infection was defined by either a runny nose or a blocked nose for more than one day, with or without a cough. An illness episode was counted as a new episode when symptoms occurred after three symptom-free days of normal activity. The author found a higher rate of illness in the child's second year of life than in their first year. For children in child care centres, the incidence in their first three years of life was 6.3, 7.2 and 6.5 respectively. Except for the children's first year, the rates are similar to those reported by Schwartz et al. Unfortunately Wald et al did not report illness after three years, and it is possible that the incidence of disease may have decreased further as was shown by Schwartz et al.

Kotch et al in an intervention study in 1988 reported a much higher incidence of illness[3]. Their method of surveillance of illness was fortnightly telephone interviews with parents, and they presented a clear case definition. In children aged 24 months of age or under in control centres, there were 15.7 respiratory illness episodes per child year. The rate reported for children between 24 months and 36 months of age was 11.8 per child year. However, these high rates were of "respiratory illness" episodes and were not specifically identified as "infection". The case definition was very sensitive: any of the respiratory symptoms of cough, runny nose, wheezing, sore throat or earache for one day was accepted as respiratory illness. Thus a child with only cough for a day would be recorded as having respiratory illness. There was no indicator that this illness was infection. Reports of cough or wheeze alone are likely to represent episodes of reactive airways disease; asthma. The rates of illness from these respiratory episodes are therefore not comparable to those reported by Wald and Schwartz.

Kotch et al also reported rates of "severe" respiratory illness[3]. Severe respiratory illness included the definition used above along with the presence of fever. This definition reshaped the illness report to be more likely to be that of an infection, however in the process it became a specific definition with the requirement of reports of fever by parents. It is not surprising that the rates reported on the basis of this definition were considerably lower than rates reported in other studies. With this more specific definition the incidence was 4.9 per child year in children 24 months of age and younger and 3.9 per child year in children over 24 months of age. Although the rates were lower than others reported, the pattern of a higher incidence in younger children remained.

In France, Collet et al reported a similarly low rate of 4.2 acute respiratory infections per child year in children under three years of age . They also used a specific case definition that involved three of more days of any respiratory symptom that resulted in treatment and a symptom free interval of seven days for a new episode[10]. The process of surveillance in the French work comprised interviews with parents every six weeks. It is possible that the lower rate detected in this work resulted from a poor recall of illness by parents because of the long

time span between interviews; and the requirement of treatment in the case definition.

Relevance to Australia

No studies have published the incidence of acute respiratory infection in children who attend care in Australia. Few of the overseas studies of infection in children in child care have published details about the child care environment that enable comparisons with our care settings.

The risk of repeated respiratory infection is likely to be higher where children mix in large groups throughout the day. Similarly, the ratio of the number of staff to the number of children they care for is likely to affect the staff members' ability to implement hygienic practices. Descriptions of the FPG centre by Loda and Denny reveal that the group size for older children differs from long-day care centres in Australia[61,62]. The FPG facility is also separated into different buildings, a rare construction for child care centres in the Australia. Descriptions of the FPG centre were that 12 children were cared for in a nursery with one staff member for every three children. This is similar to the situation in Australia where in the Australian Capital Territory (ACT) there are most frequently 10 to 15 children in a nursery, with one staff member to five children. However, for the one to four year age group, the FPG centre has only five children to one staff member and no group has more than five. In the ACT, in children of three or four years of age there is only one staff member to 12 children with a group size of 25 or more children. The larger group sizes and the fewer staff to the number of children in centres in the ACT may facilitate higher rates of disease in the ACT than reported in the FPG centre.

Although there have been no longitudinal studies yet in Australia, there is evidence of the influence of child care attendance on acute respiratory illness. Woodward et al in 1985 conducted a case control study of children prone and not prone to respiratory illness as calculated by parent report of respiratory illness in the previous year. Children prone to respiratory illness were more likely to attend child care centres than children who were not prone (adjusted odds ratio 2.23; 95 per cent confidence interval 1.38-3.61)[66].

Children in child care have more acute respiratory infections than children at home

Comparative incidence

The incidence of acute upper respiratory infection in children in child care centres is higher than in their peers who do not attend out of home care. However, there were methodological limitations in many of the early studies that compared rates in children in different types of care. These limitations included use of inappropriate control groups, and different methods of surveillance between types of care.

Early suggestion of a higher rate of respiratory illness in children attending child care "nursery schools" was made in a 41 week study in the early 1960s. Beem et al stated the "observed incidence of acute illness considerably exceeded that recorded for children of a similar age in household settings": that is Beem et al compared their observed child care incidence with other community studies[67].

By contrast, in the early 1970s rates of respiratory infection in children attending child care were considered by some to be similar to children not attending out of home care. Loda et al found increased rates of respiratory illness only in children less than one year of age who attended child care. They argued that the overall rate of respiratory illness of 8.4 per child per year was similar to respiratory illness in a different cohort, the Cleveland Family Study[61]. However, the small group size in the centre used in the Loda study and attendance at a unique centre (FPG, centre) may have contributed to a lower rate of respiratory disease in children over one year of age. Similarly in the 1970s Doyle in Canada suggested upper respiratory tract illness occurred only more frequently in children under 13 months of age in child care centres than in children at home[68].

Direct comparison of rates of upper respiratory infection between children who attend child care and children cared for at home was first undertaken in a prospective study by Strangert in Sweden in 1976 (Table 2.8). Strangert identified a higher rate of acute upper respiratory infection in children under two years of age in child care centres compared with those at home. The rate of

disease in children in long day care was higher than in children who did not attend out of home care. However, this study was methodologically flawed by its more active surveillance of infections in children in long day care[64]. A similar flaw was present in a study from France with different surveillance for type of care. Collet et al found the risk of respiratory infection declined from its highest in small child care centres, decreasing to large child care centres, and least of all in children at home[10].

In two population studies by Fleming and Hurwitz, children who attended child care were more likely to have symptoms of upper respiratory infection in the preceding two weeks than those who did not attend care[69,70]. However, Hurwtiz found that the risk in children over 17 months of age was only present if the child did not have an older sibling. Both these studies may have been subject to parental recall bias. That is, parents of children in child care may have been more likely to recall recent illness because of the impact on the parents' work role.

The methodological problems in these works comparing children in child care with those at home were overcome in the longitudinal study Wald commenced in 1985[71]. In this study, surveillance of illness in children was identical in all types of care with maintenance of parental diaries and fortnightly telephone contact. Children who remained in their care group from enrolment at birth were included in the analysis. The rate of acute respiratory infection ranged from 3.9 per child year in children who did not attend out of home care to 6.3 per child per year in children in child care centres (Table 2.8). The third year of the Wald study revealed a trend to stabilised rates of infection in children who had been in care for three years. In the third year of care, the previously significant differences compared to children at home were no longer present[65]. The Wald longitudinal study confirmed that children in child care do have a higher incidence of respiratory infection than children at home, at least in the first few years of their life.

Table 2.8 Comparison of incidence of acute respiratory infection per child year between children who attend child care centres and those who did not attend child care (Home)

Author	Year	Age group	Child care centre	Home
Strangert*[64]	1976	< 2 years	7.5	3.0
Collet*[10]	1994	< 3 years	Small centre 5.2†	0.9
			Large centre 4.2	
Wald[71]	1988	< 18 months	6.3	3.9

*Methodologically limited by more active surveillance of children in child care centres
†Small centre 10 to 20 children, large centre 40 or more children

Risk of infection is higher in children who are new to care

Children who are new to attending child care have a higher risk of infection than children who have been present in care for some time. In the Hurwitz population survey exposure to child care for less than nine months was associated with a two times greater risk of respiratory illness than attendance at child care for longer than nine months[70]. In France, children who had attended child care for less than three to six months were at highest risk of infection[10]. It is likely that this protective effect of having been exposed longer to child care comes from an acquisition of immunity to infection. As in overseas studies, Woodward showed that the risk of respiratory illness in children in child care in Australia was greater the younger the children were when they first attended child care[66].

Children in child care have a longer duration of illness

The duration of illness from acute upper respiratory infections is longer in children who attend child care than children who stay at home. In the longitudinal study by Wald et al, in every age group, children in home care with simple acute upper respiratory infection recovered more quickly than children in child care[72]. The mean duration of an upper respiratory tract infection varied from 6.6 days for children aged one year and cared for at home, to 8.9 days for children younger

than one year who attended child care. The definition of recovery from respiratory infection was identical in the two groups.

Table 2.9 Mean duration of acute upper respiratory infection in days by age group and type of care (Wald et al) [72]

Age group	Child care centre	Home
< 1 year	8.9	7.3
1-2 years	7.3	6.6
2-3 years	7.9	6.8

Children in child care were more likely than children in home care to have protracted respiratory symptoms, that is more than 15 days of respiratory symptoms (Table 2.10). Nearly twice as many children in child care compared with those in home care experienced upper respiratory symptoms for more than 15 days in the second and third years of life. Wald et al considered that the number of children with respiratory symptoms beyond 15 days approximated the number of children who may be experiencing acute sinusitis[72].

Table 2.10 Percentage of acute upper respiratory tract infections persisting more than 15 days by age group and type of care (Wald et al) [72]

Age Group	Child care centre	Home
< 1 year	11.2	8.4
1 - 2 years	10.6	6.5
2 - 3 years	13.1	6.5

Attributable risk

Approximately one third of upper respiratory infections in children who attend child care are attributable to their child care attendance[69,70]. Two population studies determined both the attributable risk of acute upper respiratory infection from child care attendance and the population attributable risk for child care attendance on respiratory infections in the entire population of children. Fleming interviewed parents of approximately 500 children in Atlanta, USA in 1987. The study was conducted over three months in summer and autumn. The definition of

attendance at child care was more than four hours of supervised regular care per week together with at least two unrelated children. This definition is generous and would classify more children as child care attendees than other studies. Hurwitz undertook a national survey of nearly 3,500 children in the USA. This national survey was conducted in the spring and summer between March and June 1993. Both studies used telephone interviews to ask about infectious illness and child care attendance in the two weeks prior to interview. Hurwitz defined child care attendance as having child care with at least one unrelated child for at least 10 hours per week in each of the four weeks before interview. There is a potential bias in both of these studies, namely that parents of children who attend child care may be more likely to report illness in their children than parents of children at home.

After adjusting for other variables, Fleming reported that the overall attributable risk of upper respiratory infection from child care was 31 per cent. This differed minimally by age, being 30 per cent for children younger than three years of age and 33 per cent for children over three years of age. A similar attributable risk was found by Hurwitz: 28 per cent in children six weeks to 17 months of age, 33 per cent in children 18 to 35 months of age, and 18 per cent in children 36 to 59 months of age.

Population attributable risk

Both Fleming and Hurwitz estimated the population attributable risk for acute upper respiratory infection: in all children under five years of age, between seven to 12 per cent of acute upper respiratory infections may result from child care attendance. In the Atlanta study, the population attributable risk for acute upper respiratory infection and child care attendance was nine per cent for children under three years of age, and 11 per cent for children over three years of age. In the national study, the population attributable risk was 7.1 per cent in the age group six weeks to 17 months, 11.7 per cent in the age group 18 to 35 months and 7.7 per cent in the age group 36 to 59 months. The similarity of the population attributable risk of seven per cent in the youngest and oldest groups reflects a higher proportion of children exposed in the older group. The attributable risk was quite different between these two groups, being 28 per cent

in the youngest and 18 per cent in the oldest group. More children from the oldest group attend child care; therefore, although the attributable risk was lower, the population attributable risk was similar to very young children.

Secondary infections in families

Children have long been recognised as responsible for introducing respiratory infections into families[73]. At the time of the Cleveland family study in the 1950s, the illness was primarily introduced by school-aged children. Few children at that time attended care in group arrangements[74]. This pattern is likely to be different when children of younger ages come to mix in groups.

Agents of respiratory infection in child care

The same organisms that cause acute upper respiratory infections in children in child care do so in children at home. Agents responsible for acute upper respiratory infection have been identified since 1966 in cohorts of children attending the Frank Porter Graham Centre (FPG) at the University of North Carolina[61-63]. The most frequent isolates were respiratory syncytial virus, parainfluenza viruses (type 3 predominantly), adenoviruses (type 1 predominantly), enteroviruses and rhinoviruses. Influenza viruses were isolated less frequently. The seasonal patterns of viruses isolated in the centre correlated with the presence of the contemporary community isolates.

In France, Aymard identified these same respiratory pathogens in 780 children in a child care centre[75]. Respiratory syncytial virus caused one third of all respiratory tract infections in children attending child care in France and was the most important single causative agent. For reasons that are unclear, influenza A and B were less frequently isolated in children in child care centres than in children who attended general practices. In addition to the viruses reported in children at the FPG Centre, coronavirus was isolated from children in Aymard's study. In one winter, coronavirus caused recurrent epidemic events and was the predominant respiratory virus isolated. The addition of coronavirus to the

repertoire of respiratory pathogens in children who attend child care is likely to be an effect of recently improved methods for the detection of coronavirus.

Transmission of respiratory viruses

The methods of spread of the predominant respiratory viruses in child care are not completely understood, and each virus may not spread in the same manner[76]. The possible methods of transmission of respiratory viruses are by:

1. infectious small particle nuclei (less then 10 microns) suspended in air, which are then inhaled by the new host; or
2. large particle droplets (10 microns or more) briefly transported through air which may be inhaled by a host who is close, or may contaminate surfaces that a new host then touches; or
3. respiratory secretions contaminating fomites, which new hosts may touch and directly inoculate themselves by contact with their nasal membrane or conjunctiva.

Infection in a susceptible host may result from the spread by a combination of these three routes. Understanding how respiratory viruses are transferred may suggest methods of reducing spread in child care.

Respiratory syncytial virus

RSV is commonly isolated from symptomatic children in child care[61-63]. It is reported as the most important single causative agent of respiratory tract infections in child care, and the introduction of RSV into child care has been shown to result in extensive spread[67,75].

The transmission of RSV has been studied in nosocomial outbreaks and although the environment is different from child care, these hospital outbreaks provide a substantial body of evidence about RSV spread in groups. Hall, Douglas and others have published a series of studies on the transmission of RSV[77-80]. In a 1975 study of nosocomial infections, they concluded that staff appeared to play a major role as virus carriers. During nosocomial outbreaks, close to 50 per cent of adult hospital workers acquired RSV infection[77,78,81]. Hall et all sought to investigate the role of fomites in transmission. They established that RSV could

survive in the environment for different amounts of time depending on the surface[79]. RSV survived on countertops for up to seven hours and on gloves for five hours and infectious virus was recovered on cloth after two hours but survival diminished on skin and paper tissues to an average of 30 minutes The authors showed that not only was the virus recoverable from the fomites, it was transmissible. RSV on countertops was transferred to hands touching the contaminated surfaces and could be recovered from those hands for up to 25 minutes later. The virus was also recovered from the skin after contact with contaminated paper tissues, for an average of three to 10 minutes. Hall et al concluded in this early study that "good handwashing would seem of prime importance" and that objects potentially contaminated by secretions should be recognised as possibly contagious.

Hall et al went on to study the experimental transmission of RSV to volunteer adults by three methods of contact[80]. The volunteer adults were grouped as:

a) "cuddlers", those with normal caring contact with the children;

b) "touchers", those who were exposed to objects while the infant was out of the room —/ this group touched objects usually found about an infant's bed and then touched the mucous membranes of their nose or eye; and

c) "sitters", those who were exposed to an infant two metres away and were only allowed to read in the room.

Infection was only acquired in the cuddlers' and touchers' groups. The cuddlers may have acquired infection by all three of the potential routes: small particle aerosol, large particle droplets, or contact with fomites. The touchers group could only acquire infection by fomite contact and direct inoculation. There was no transmission by inhalation of small particle aerosol in the sitters group. The authors concluded that the spread of RSV may have occurred by close contact with direct inhalation of large droplets or by self inoculation after touching contaminated surfaces, and that infection control procedure for RSV should stress handwashing[80]. These studies suggest that infection control methods that aim to remove RSV particles from hands or to prevent hand contamination with RSV may reduce transmission of RSV.

Rhinovirus

The transmission of rhinovirus, another common virus that induces a cold, has been extensively studied. However, the results of these studies do not provide consistent evidence about the relative importance of transmission by direct contact compared with aerosol transfer. Shedding of rhinovirus in nasal secretions is highest when symptoms are present, but small quantities of the virus may be continued to be secreted from the nose for 14 to 21 days[82]. Rhinovirus contamination of fingers is common in the acute stages of cold, in one study the virus was present on fingers of 42 per cent (16/38) of volunteers with acute colds[83]. Furthermore, rhinovirus has been shown to survive on environmental surfaces and skin for one hour or more and volunteers touching surfaces containing dried rhinovirus have infected themselves by touching their nasal or conjunctival mucosa[84]. Transmission has also been shown experimentally by contact with rhinovirus on plastic objects[85].

These studies have particular relevance to child care where an important group of fomites is toys. Experimentally contaminated donor hands that contaminated a door knob or tap were studied in a series by Pancic[86]. Rhinovirus was acquired by recipients who touched the fomite, and the average amount of rhinovirus recovered from recipients was 13 per cent of the amount recoverable from the fingers of the donor. The authors suggested that a high concentration of virus might be expected if the donor hand was that of a young child who did not use a tissue or handkerchief. Recently Ansari et al studied virus survival on fingertips and stainless steel fomites[87]. As in other studies, they found that rhinovirus survived on hands and fomites. Despite the type of donor or recipient surface, transfer of infectious virus 20 minutes after deposition was between 0.7 and 0.9 per cent. These results suggest a role for nonporous environmental surfaces in the contamination of hands with rhinovirus.

An early study of hand to hand transmission of rhinovirus colds showed that transmission of infection was very efficient by the hand route. Infection was transmitted in 11 of 15 hand contact exposures, in only one in 12 large particle droplet exposures and in no small particle aerosol exposures. When the virus was detected on a donor's hands, it was also recovered from 71 per cent of recipients

hands[88]. Looking closely at the methods of experimental transmission, the rhinovirus donors in this study contaminated their hands as they would when blowing their noses. Visible moisture or mucous was present on some but not all contaminated hands. The recipients then touched the donor hands for 10 seconds. Moisture and mucous were not usually visible on recipients' hands. The recipients inoculated themselves by placing their fingers on nasal and conjunctival mucosa, as they might under natural conditions. This study is relevant to child care where staff members hold tissues for children to blow or where staff wipe a child's nose.

However, not all investigators agree with the role of fomites in transmission of rhinovirus. Jennings in 1988 showed the reduction of viable virus along a fomite chain[89]. From initially high concentrations from nasal washings and finger tips, little virus was detected on fomite and recipients' fingers. The transfer of viable virus was highest when secretions were transferred within one minute, that is when they were not yet dry. Jennings found that very little virus reached recipients' fingers and that almost no virus was recovered from their external nares despite enforced hand to face contact. Autoinoculation by hand contact with conjunctiva, as performed in other experimental transmission studies, was not attempted in this study[89]. Reed studied hand contamination in volunteers and their flat mates[83]. Low titres of virus were found on surrounding objects, but the authors concluded that a recipient might pick up enough virus on their fingers by direct contact with heavily infected skin or secretions to constitute a risk of self-inoculation via the conjunctiva or nostril.

Dick et al in 1987 found rates of infection by the aerosol route alone (53 per cent) were similar to rates of infection by any one of aerosol, direct contact or fomite contact routes (67 per cent). Furthermore, unlike Gwaltney's experiment, Dick et al were unable to induce infection by fomite contact alone. They concluded that "at least in adults", rhinovirus transmission occurred chiefly by the aerosol route. Dick and Jennings argued that the earlier studies showing the efficiency of hand transfer over aerosol did not allow for adequate duration and intensity of duration of donor to recipient aerosol transfer. They also stated that

"we believe also that direct inoculation of fresh nasal secretions is an infrequent occurrence, likely to occur only in situations of intimate contact with young children with severe colds during cuddling or inadvertently by parents who have just wiped an infant's nose"[90,91]. Such contact is readily observable in child care centres.

Although the method of transmission of rhinovirus remains controversial, authors who highlight the importance of aerosol transmission carefully describe the importance of this route in adults rather than children. Child care is a unique transmission environment where large number of donor exposure hours may accumulate, wiping of noses is performed by a number of adults as well as by children, and children share many fomites in the form of toys.

Other respiratory viruses

The spread of all three parainfluenza serotypes has been shown in child care settings[61]. Small particle aerosols probably do not play a major role in the spread of parainfluenza viruses. McLean et al detected few small particle aerosols in an experimental setting: viable virus was found in only one of 30 air samples within 60 cm of patients with natural infection who were known to be shedding virus[92]. However, if direct contact is an important transmission route for this virus, contact probably needs to occur quickly because in one study parainfluenza 3 infectivity was rapidly lost on hands[87].

Influenza virus is likely to be spread by small particle aerosols. Influenza type A has been shown to be relatively stable in small particle aerosols, particularly in low humidity and low temperature[93]. In experimental situations, far larger doses are required to infect by nasal drops, simulating direct inoculation, than by aerosol route[94,95]. Evidence about the mode of transmission of other respiratory viruses such as adenovirus and coronavirus is lacking in the literature.

Duration of contact

Researchers stress that the duration of contact with symptomatic respiratory virus donors is an important factor in whether the virus is transmitted to a new host. In

experimental situations transmission of rhinovirus depends on: the degree of donor symptomatology, the level of virus shed by the donor, the issue of whether the donor had virus on his hands and nose, and the amount of time that the donor and the recipient spend together[96,97]. In a model for transmission of rhinoviruses, Meschievitz found the rate of transmission to recipients was directly proportional to the aggregate number of hours that they interacted with donors. A 50 per cent transmission rate was predicted to occur at approximately 200 donor hours of exposure[98]. The risk of transmission of respiratory infection between children in child care is potentially large partly because they spend large numbers of hours interacting with possible virus donors. If Meschievitz's rate model were applied to child care, four symptomatic children for one week would provide 200 donor hours. If four symptomatic donors were in a care group of 20 children, a transmission rate of 50 per cent in the asymptomatic children would result in eight new cases. Of course, this model does not allow for consideration of the child's immunity to infection nor to contact with other donors outside the study group. However, it does highlight the risk of transmission of respiratory infection between children in child care because they potentially have large numbers of hours interacting with donors.

Reducing the spread of respiratory viruses

Two intervention studies

Two studies have estimated the impact of a hygiene intervention on the spread of respiratory viruses in child care settings[60]. Butz et al found that hygiene training in family child care homes did not reduce the number of days that children had runny noses, although the number of days of gastrointestinal symptoms was decreased. Kotch et al similarly found that their hygiene intervention had no impact on episodes of respiratory illness[3]. They stated that the intervention addressed the handwashing of children and the handling of respiratory secretions by staff, but it is not clear if they developed a procedure for how a nose should be wiped.

Nose wiping material

Unlike practices that lead to diarrhoeal disease in child care centres, practices that are a clear risk for viral respiratory infections have not been identified. However, the use of cloth handkerchiefs or tissues in child care centres was shown to be relevant for invasive *Haemophilus influenzae* disease. In child care centres with cases of invasive disease, staff were five times more likely to use towels or handkerchiefs to wipe children's noses than in control centres[99]. Murphy et al found *Haemophilus influenzae* type b in nasal mucous of children, and on wash rags, in child care and concluded there was need for care in the management of nasal mucous secretions in child care[100].

Without evidence of child care risk practices affecting respiratory disease, consideration of the prevention of respiratory disease requires evidence from experimental and other settings. In 1986, Dick et al showed that in experimental situations virucidal tissues reduced transmission of rhinovirus infection. Volunteers used either tissues impregnated with citric acid, malic acid and sodium lauryl sulphate or cotton handkerchiefs. In card playing experiments, 14 of 24 recipients (58.3 per cent) playing with donors using cotton handkerchiefs became infected compared with none of the recipients in contact with donors using virucidal tissue[101]. Similarly, Hayden showed that fingers of a person with a rhinoviral cold are usually contaminated during finger to nose contact, that the use of a thicker tissue reduced finger contamination, and that a virucidal tissue almost eliminated contamination[102,103]. However, when a similar intervention was transferred to a home setting by Longini et al, virucidal nasal tissue use only partially interrupted the transmission of respiratory agents[104]. The maximum efficacy of the treated tissue was 36 per cent. The efficacy of the tissue may have been limited by the type of virus circulating at the time the trial was performed, at a time when influenza virus (aerosol spread) was more prominent than rhinovirus. Also, the placebo tissues were thicker than the normal tissue used. The placebo tissue was three ply, mimicking the treated tissue but without the virucidal substance in the middle layer. The placebo tissues themselves were therefore likely to act as a barrier to the contamination of hands and fomites. In a second natural setting, Farr et al also found that virucidal tissues were less effective in preventing transmission than in experimental settings[105]. They

suggested one reason for this reduced effectiveness in the field was poor compliance by children in the use of virucidal tissues for nose blowing and covering coughs and sneezes.

Disinfectants

The use of disinfectants on hands has not been very successful in reducing the spread of respiratory infections. There are limited numbers of disinfectants that are able to be used on hands without causing unacceptable discolouration or drying. Each disinfectant requires exposure time and concentration to enable disinfection. Alcohol may be rubbed on hands or applied in a foam and allowed to air dry. Alcohol will kill viruses that have a lipid envelope present, such as respiratory syncytial virus, parainfluenza, influenza and coronavirus but will have little effect on viruses with no envelope. Diluted solutions of iodine have been shown to be effective against rhinovirus on the skin[106,107].

Aqueous iodine applied to the fingers blocked hand transmission of rhinovirus for up to two hours after application in an experimental situation[108]. Hendley et al reported that iodine used on mothers fingers significantly reduced the transmission of colds from children to mothers in households[109]. However, the number of secondary infections was small, over four years there were 4 secondary infections of 58 occurrences (7 per cent) in the iodine group compared with 16 secondary infections from 79 occurrences (20 per cent) in the placebo group. Although there was some impact, it is unfortunate that the cosmetic appearance of iodine makes it impractical for routine use.

In 1984, the treatment of fingers with another disinfectant was tried, a lotion containing two per cent glutaric acid which inactivated rhinovirus serotype 2[110]. This lotion was more effective than placebo in inactivating experimental virus and the activity persisted for up to six hours after applications. However, the long lasting effect was seen only in volunteers who had limited hand activity. With normal physical activity of hands, the virucidal effect was reduced.

Reducing susceptibility

The development of respiratory illness is dependent upon the transmission of respiratory viruses and the susceptibility of the recipient. Non-specific immunostimulation through vaccination of children has been attempted, but it is unsuccessful at maintenance of immunity[75,111].

Discussion

There is no doubt that children who attend child care centres suffer from more acute infections than do their peers at home. The morbidity from these infections is not limited to the children alone, as they act as conduits for the introduction of diarrhoeal and respiratory infections into their homes.

The research that has been done to date gives us some information about which children are at higher risk of infections and a few child care practices that increase this risk. Children who are young, who are new to a child care centre, and who are cared for in larger groups, acquire more infections than others. For diarrhoeal infections, combining toilet and non-toilet trained children increases the rate of communicable disease, as does combining the staff functions of nappy changing and food serving. However, these results provide few practical options for reducing the transmission of infections. We cannot change the age of children or their newness to enrolment; and group size is limited by the affordability of child care. Children in many child care settings are separated by age, thereby separating toilet trained from non-toilet trained children, but they frequently mix together at the beginning and end of the day when the number of children in the centre is small. The separating of the staff functions of nappy changing and food serving would appear to be beneficial if amenable to change, but in practice this may be difficult in a routine where there are few carers who perform all the child's care jobs.

The opportunities to reduce respiratory infections in child care are even less clear than the case of diarrhoeal infections, but there is one appealing possibility. While the evidence about how respiratory viruses are transferred from donor to host is mixed, there is a pervasive theme in the research that direct transfer by hand contact may be more important in children than in adults. Furthermore, for the single most frequent virus in child care, RSV, both direct transfer and fomite contamination play a clear role in transmission. If direct transmission is

important in child care, the manner in which children's respiratory secretions are handled may impact on the number of respiratory infections that children acquire.

The gap in the literature is therefore the lack of evidence about what practices may be used by child care workers to reduce the transmission of infections. No study has evaluated comprehensively whether its training intervention produced the desired behaviours. We are not, then, able to conclude whether a failed intervention was a result of the failure of the practices to reduce disease, or result of the failure of the intervention to change practices. Only the results from the Kotch intervention trial are worthy of consideration because of the methodological rigour of the trial, but these results were disappointing. Kotch reported a reduction of diarrhoea, but only in episodes of severe diarrhoea in young children, and their intervention had no impact on acute respiratory infection. What the authors considered may have limited their impact was a lack of attention of the intervention to children's behaviour as well as to adults behaviour.

To be able to convince child care staff to alter their routines and behaviour we need evidence that this change will benefit the children. Likewise, to be able to commit funds to training child care staff we need evidence that such training can lead to the performance of effective infection control practices. Hence I developed the following research questions:

1. Can training child care staff enhance the recommended infection control behaviours of staff and children?
2. Can the recommended behaviours reduce episodes of acute respiratory and diarrhoeal infection in the children in this environment?

Chapter 3 Methods

Overview

The study of infection control intervention in child care centres was designed as a randomised controlled trial. I selected this study design because it provided the best method to answer the research questions. The study population was children who attended large long child care centres in the ACT. The unit for randomisation and intervention was a child care centre and the period of the study was nine months: from March until November 1996. I conducted the training about infection control in all centres. Staff in intervention centres were trained at the beginning of the trial, and I reinforced this training by visits throughout the trial. I trained the staff in the control centres after the cessation of surveillance of illness in November 1996. Surveillance of illness in children was conducted by fortnightly telephone interviews with the children's parents. The performance of hygiene practices in both intervention and control centres was recorded throughout the trial by one observer.

The trial was approved by the Ethics Committee of the Australian National University on 5 October 1995, and modifications to the study design to incorporate telephone interviews were approved on 7 February 1996 (Appendix 1). I sought funding from the Commonwealth Department of Health and Family Services, Research and Development Grant Program in April 1995. I was notified that the funding application was successful on 1 January 1996 (Appendix 2).

Study population

The study population comprised children who attended large long day care centres in the ACT. I included only long day care centres licensed to care for 50 or more children. The license conditions for long day care regulate the number of children that a centre may care for up to a maximum of 11 hours per day. These centres do not provide care for children on an occasional basis. The license conditions include staff to child ratios and staff qualifications. I chose only centres that cared for 50 or more children because the incidence of illness in children has been reported to be higher in centres that provide care for higher numbers of children [1]. In addition, I elected to study the intervention in long day care centres where children were separated by age group. Although in some centres, children of different ages are grouped together, in accordance with vertical or family grouping , this practice is less common than age segregation.

I established three eligibility criteria for children in the trial. First, children must have been under four years of age at 1 January 1996. I selected this age group because of published evidence that younger children had higher rates of disease than older children in care (Chapter 2). By including only younger children I was more likely to obtain a sample with a sufficient high incidence of disease to enable detection of any decrease in illness with reasonable power. Second, I limited participation to children who attended care for three or more days per week in order to ensure that the children had the opportunity to be exposed to infections within the centre. Third, I excluded children who had any chronic illness that predisposed them to infection.

Sample size estimation

To determine the required sample for the study, I specified:

1. the anticipated rate of infections;
2. the anticipated effect of the intervention;
3. the impact of the cluster design;
4. power; and
5. confidence.

Anticipated rate of infections

Children under five years of age in child care acquire approximately seven upper respiratory tract infections per year. The rate in children under four years of age was reported as 8.4 per child year by Loda et al and 6.8 per child year by Schwartz et al[61,63]. For the purpose of sample size estimation I anticipated rates of seven and eight episodes of acute respiratory infection per child year. The mean value of published rates for diarrhoeal disease used for sample size estimation was 1.4 per child per year and I considered considered rates from 1.4 to three per child year (Chapter 2).

Anticipated intervention effect

Diarrhoeal infection

A 50 per cent decrease of diarrhoeal disease in child care was shown following a hygiene training intervention[5]. Whilst this study was the first of its kind, it did not allow for the effect of any confounding factors on illness in children. In a recent comprehensive study allowing for confounding, Kotch et al showed a significant decrease in severe diarrhoea in children under two years, being a 50 per cent reduction from 1.33 per child year to 0.67 per child year [3]. Total episodes of diarrhoea in all children were decreased by 16.5 per cent, but this was not a statistically significant finding. The incidence was 4.73 episodes per child per year in the control centres. For the purpose of sample size estimation, I considered a minimum reduction in the rate of diarrhoea of between 10 and 25

per cent worthy of detection, from background rates of diarrhoeal disease of 1.4 to three per child year (Table 3.1).

I estimated the sample size requiring 80 per cent power and using a test of five per cent significance level. To calculate this estimate I used the equation for the comparison of two rates where the sample size of each group is given by:

$$\frac{(u + v)^2 (u_1 + u_2)}{(u_1 - u_2)^2}$$

where u_1 and u_2 are rates of infection in the two groups; u represents power, the one sided percentage point of the normal distribution corresponding to 100 per cent; and v is the significance level, the percentage point of the normal distribution corresponding to the two sided significance level [112].

Table 3.1 Estimated sample size with 95 per cent confidence and 80 per cent power for detecting a reduction in the rate of diarrhoeal infection

Background rate	Percentage effect of intervention	Child years of observation
1.4	**25**	**314**
1.4	20	504
1.4	10	2128
2	25	108
2	20	353
2	10	1490
3	25	146
3	20	235
3	10	993

Respiratory infection

Respiratory infections in children in child care have not been reduced in any intervention study to date. The question of what impact the intervention could have on disease depends partly on what proportion of infections may be acquired from child care attendance. Clearly, all respiratory illness in children cannot be attributed to their attendance at care. Two population studies show the attributable risk for upper respiratory infection in children who attend child care to be approximately 30 per cent [69,70]. Thus, if one third of children's colds were attributable to their care attendance, what proportion of these could be reduced by

the intervention? I considered that an impact of the intervention of between 10 and 15 per cent was clinically worthy of detection from background rates of respiratory disease of seven to eight per child year (Table 3.2).

Table 3.2 Sample size estimate with 95 per cent confidence and 80 per cent power for detecting a reduction in the rate of respiratory infection

Background rate	Percentage effect of intervention	Required child years of observation
8	10	372
8	**11**	**306**
8	13	217
8	15	161
7	10	426
7	11	350
7	13	248
7	15	184

I elected to use a preliminary sample size of 314 child years of observation. This would encompass:

- 314 child years for detecting a 25 per cent decrease in diarrhoea from a background rate of 1.4 episodes of diarrhoea per child per year (refer bold type in Table 3.1); and
- 306 child years for detecting an 11 per cent reduction in respiratory illness from a background rate of eight respiratory infections per child year (refer bold type in Table 3.2).

As the rate of respiratory and diarrhoeal infections in children who attend Australian child care centres is unknown, I assessed the power of this study to detect decreases in infection from differing background rates of disease (Tables 3.3 and 3.4). This sample size has adequate power to detect the differences in "severe"and "all" diarrhoea detected in the Kotch intervention study[3].

Table 3.3 Power to detect a decrease in the incidence of episodes of respiratory illness with 314 child years of observation

Rate of respiratory illness (episodes per year)	Reduction in respiratory illness (per cent)	Power (per cent)
7	11	76
8	11	80
9	10	78
10	10	82
11	9	77

Table 3.4 Power to detect a decrease in the incidence of episodes of diarrhoeal illness with 314 child years of observation

Rate of diarrhoeal illness (episodes per year)	Reduction in diarrhoeal illness (per cent)	Power (per cent)
1.33	50	>99*
1.4	25	80
2	20	75
3	18	83
4	15	80
4.76	16.5	91*

* Rate and reduction from Kotch intervention study

The trial was conducted over nine months to avoid the summer holiday season when children may be away from care, to minimise parent load and to incorporate peak periods of viral infections. The sample estimate was therefore adjusted for a nine month period of surveillance. The crude estimate of sample size for nine months was calculated as follows:

$$x \text{ children} * 9 \text{ months} = 320 \text{ children} * 12 \text{ months}$$

$$x \text{ children} = (314 * 12)\ 9$$

The sample estimate of 314 child years is equivalent to 419 children for nine months of observation.

Increase in sample to allow for cluster design

Randomisation to intervention and control groups in this trial was randomisation by cluster, each cluster being a child care centre. The intervention was at the level of the cluster, not the individual. Each child in a cluster randomised study may contribute less information than if each child had been individually randomised; that is, the responses for each child in a cluster cannot be regarded as statistically independent. To allow for this, I increased the sample size by an inflation factor. This accounted for the level of within cluster resemblance.

The inflation factor is dependent upon the number of clusters and the intracluster correlation coefficient. A correlation coefficient of 0 indicates total independence; that is, there would be no effect on each child from being in the cluster. On the other hand a coefficient of 1 indicates total agreement, as would be the case if each child were identical to another child in their incidence of disease. Estimates of the coefficient for infections in children in child care were not available. However, I obtained the correlation coefficient for respiratory infections in children in school class rooms from a study performed by Pilotto (in personal communication from Robyn Attewell and Louis Pilotto, National Centre for Epidemiology and Population Health, ANU). The correlation coefficient was 0.01. The formula for the inflation factor as provided by Donner and Hysieh [113,114] is:

$$IF = 1 + (m-1)\,r$$

where IF = *inflation factor*

m = *the number of people per cluster and*

r = *the intracluster correlation coefficient.*

The relationship between the number of clusters and the intracluster correlation coefficient can be seen in Table 3.5. With a fixed inflation factor of 1.3, increasing the number of child care centres (clusters) from 10 to 20 translates to a change in the intracluster correlation coefficient from 0.006 to 0.011. For this intervention trial, the number of clusters was limited by the number of child care centres in which I would have been able to conduct the intervention. I decided

that approximately 20 centres was attainable, being 10 intervention and 10 control centres.

Table 3.5 Comparison of the effect of the inflation factor, number of clusters and intracluster correlation coefficient

Inflation Factor	Sample allowing clustering*	Number of clusters	m †	rho‡
1.3	545	10	55	0.006
1.3	545	15	36	0.009
1.3	**545**	**20**	**27**	**0.011**
1.4	586	10	59	0.007
1.4	586	15	39	0.011
1.4	586	20	29	0.014
1.5	628	10	63	0.008
1.5	628	15	42	0.012
1.5	628	20	32	0.016

* Crude estimate of 419 children for 9 months multiplied by the inflation factor
† Number of children per cluster
‡ Intracluster correlation coefficient

Final target sample

Using the preceding calculations (Tables 3.1 to 3.5) as a guide, I decided on a target sample of 545 children for nine months observation (408 child years), involving 20 child care centres with 27 children from each centre, allowing for an intracluster correlation coefficient of 0.011.

Sample frame

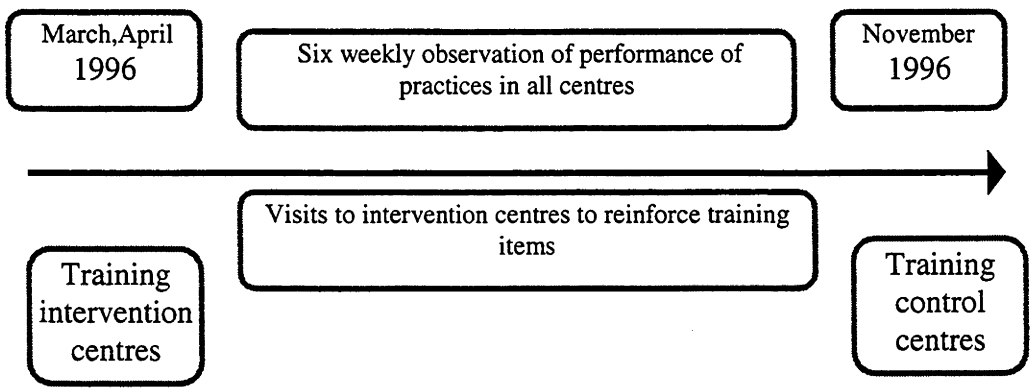
The sample frame for long day care centres comprised all those licensed to care for 50 or more children in the Australian Capital Territory at 1 February 1996. All child care centres in the ACT are licensed by the Youth and Family Services Bureau, and I obtained a list of all centres in the sample frame from the bureau. One centre was used as a pilot site where I developed and tested methods for the trial in 1995 and 1996. To recruit centres for the trial I first telephoned and then visited the directors of each centres so as to invite them to participate. A potential limitation of this design was the small size of the city from which the sample was obtained. Child care workers in one centre were likely to have contact with workers in other centres either socially, through course work or trainee classes. This meant that staff from the intervention group may have been able to pass information about the intervention to staff from the control group. The control group could therefore have become contaminated. To address this potential limitation I reviewed the study design with every child care director. I emphasised the importance of the role of control centres throughout the study. I asked that, where possible, staff in centres who were subsequently allocated to control groups would not change their practices over the trial period. The centre directors understood that if the control centres commenced using intervention practices, we would not have been able to obtain scientific proof of the effectiveness of the practices. All centre directors agreed to participate, knowing what would be involved in the alternative potential roles as intervention and control centres, before randomisation was performed.

The Trial

Timeline

The period of the study was nine months, from March until November 1996. I chose a period of nine months that included seasonal peaks of respiratory and diarrhoeal virus infections. I did this so as to limit the period of surveillance, to avoid dropout by parents, and to avoid the holiday summer months when large numbers of children may be away from care. The period incorporated seasonal peaks of common infections including: rotavirus, respiratory syncytial virus, rhinovirus and parainfluenza virus infections (personal communication and data provided by Margaret Curran, Communicable Diseases Intelligence LabVise Scheme Commonwealth Department of Health and Family Services). Surveillance of illness was carried out over 254 days from 17 March 1996 to 16 November 1996 (Figure 3.1).

Figure 3.1 Timeline of intervention training, reinforcement and observation of practices



Assignment

After all centres had agreed or declined to participate, each centre was allocated a number from one to 23. I generated a list of 12 random numbers between one and 23 in *Epi Info* [115]. Centres corresponding to randomly generated numbers were allocated intervention status. One random number was a duplicate, hence 11 intervention centres were assigned to intervention status, the remaining 12 were control status. I visited each centre to inform the director of their status within the trial.

Recruitment of parents and children

Recruitment of children commenced before I allocated centres to intervention or control status. I delivered hand signed letters for parents to each centre. The child care staff passed these letters on to the parents (Appendix 3). The parents completed the enrolment forms and returned them to the child care centres. I confirmed that each child met the eligibility criteria with the staff in the centres. From the questionnaire that had been completed by the parents, I checked that each child did not have any illness that would predispose to infection. Where parents had completed an enrolment form, but their child did not fulfil the eligibility criteria, I sent a personal letter of thanks explaining why their child could not participate. Where children were eligible to participate, I returned a personalised package to the centre with: a letter for the parent, a calendar for the first half of the trial (Appendix 4), a fridge magnet for securing the calendar and information about what the interviewers would ask at each interview. A second calendar with a personal letter was sent to parents in June 1997. I conveyed the enrolled child's name, parents' name and telephone number to the research company Datacol. Parents who had enrolled before the commencement of surveillance were telephoned by the interviewers to welcome them to the trial and to explain the procedures. Parents who enrolled after telephone surveillance had commenced received this welcome and explanation during their first interview.

Ongoing recruitment

I encouraged the recruitment of children to the trial until October 1996. On each of my visits to the intervention centres, I asked the directors to approach the parents of any child who was new to the centre. On each of the observer visits to the control centres, the observer asked the directors to try to recruit children. In addition, I telephoned the directors of the control centres each month to encourage them to continue recruitment.

Planned intervention

Objective

The objective of the intervention was the reduction of transmission of infection in child care centres by decreasing the contamination of hands and fomites.

Theoretical basis of the objective and its application to child care

Transmission of infectious disease in child care may be by the following routes:

- direct contact with organisms at the site of infection;
- indirect contact with organisms on a fomite;
- small particle aerosols that remain airborne;
- large particle droplets that fall and contaminate surrounding surfaces; and
- common vehicles such as contaminated food that is ingested.

Four of these transmission processes are potentially interrupted by the reduction of contamination of hands and fomites. Small particle aerosol transmission would not be affected by this intervention.

Because diarrhoeal pathogens are transmitted from faeces to mouths, there is an obvious potential for organisms to be transferred from contaminated fomites, hands or food to the mouth of a new host. In one study, a twofold increase in diarrhoea was shown in children in child care rooms where either faecal-hand contamination or faecal contamination on moist fomites was found [6]. Child care centres where staff combine the functions of changing nappies and preparing or

serving food have been shown to have over three times as much diarrhoea as centres where different staff perform these tasks [7]. This is presumably because staff contaminate their hands when changing nappies and pass these organisms on to children in food. Another study, found that during outbreaks of diarrhoea, faecal coliforms were recovered from hands and objects in the child care room significantly more than during other periods[52].

To be able to reduce transmission of infectious diarrhoea in child care I needed to address hand and fomite contamination with faecal organisms. I considered this may be possible by:

- washing adult's hands after using a toilet, changing a nappy, or helping a child use a toilet;
- preventing contamination of the adult's hands with faecal organisms;
- washing children's hands after using a toilet and having a nappy changed;
- preventing contamination of children's hands;
- washing of fomites likely to be contaminated with faecal organisms; and
- preventing contamination of common vehicles such as food and play dough.

The role of hand and fomite contamination in the transmission of respiratory infections is less clear and is contentious (Chapter 2). If direct transfer of respiratory viruses by hands plays a role in transmission in this setting, what particular behaviours may facilitate transmission? Direct virus contamination of a care giver's hands could occur when that carer wipes, or assists the blowing of, a child's nose. Even if a carer avoids direct contact with the child's secretions they may contact the virus through a tissue; experimentally, rhinovirus suspended in cell culture medium consistently passed through commercial tissues[103]. Although respiratory viruses do not survive on hands for long periods, the virus may be transmitted from carer to another child by contact. The carer's hand may contact another child's nasal mucous membranes or conjunctiva, as when the carer assists another child to blow their nose, or wipes an eye of a child who is crying. The carer's contaminated hand may also contaminate fomites such as tables, door knobs, taps or toys. One respiratory virus, respiratory syncytial virus, can survive

on countertops for six hours [79]. Furthermore, this virus was found on hands that touched the contaminated countertops for up to 25 minutes after contact.

Contamination of fomites with respiratory viruses may occur by virus transfer from a hand to the fomite or by large particle droplets landing on the fomite. Indirect transmission, from the fomite to the recipient, may then occur through the recipient's hand contact with the fomite, or nose or eye contact with the fomite. In the majority of settings, fomites would rarely come into contact with noses or eyes. However, this is not the case in child care. Of potential fomites, toys are the most likely to be important in disease transmission and frequent washing of fomites in day care settings could affect transmission. Yet toys are infrequently washed in Australian child care centres. In a study of 61 child care centres, toys that children put into their mouths were washed once a week in half of the centres and once a month in 40 per cent of centres[116].

How children wipe their own noses may play a role in whether respiratory infections are transmitted by the direct route in child care. Children may not use a tissue at all to wipe their nose, and may sometimes wipe their nose on their hand, on the back of their hand or in a sweeping movement along the back of their hand and forearm. Respiratory viruses in the nose secretions of children in child care primarily occurs in those who have symptoms of a cold[62]. This is in contrast to nasopharyngeal carriage of bacterial pathogens and gastrointestinal carriage of pathogens. In one study, there was a clear association of symptomatic respiratory illness with rhinovirus spread[67]. Increasing the frequency of handwashing for symptomatic children may reduce the spread by direct contact and contamination of fomites.

Children's contamination of their hands with their own nose secretions is not limited to their wiping of their runny noses. Their hands may also be in contact with respiratory secretions as a result of their placement of fingers in their noses. Numerous children's songs are devoted to identifying appropriate anatomical body parts and include direct statements such as "put your finger on your nose", "touch your nose" and include hand actions such as a hand mimicking a fly on a nose. Whilst adults may genteelly touch their noses in these action songs,

children often use less precise movements and may put their whole hand below the nose or even place a finger well inside the nose. Handwashing after such action songs would remove any contamination of children's hands.

If respiratory viruses are transmitted by hand contact in child care, the possible options for practices aimed at reducing such transmission include:

- preventing contamination of adult's hands;
- washing adult's hands after contamination with nose secretions;
- washing of fomites likely to be contaminated with respiratory secretions;
- preventing contamination of children's hands;
- ensuring care givers realise that touching a nose may help spread infections;
- washing children's hands after contamination with nose secretions; and
- ensuring symptomatic children more frequently wash their hands.

Format and timing

There were three facets to the intervention:

1. a training session for child care staff;
2. visits to the centres to reinforce the training items; and
3. a newsletter to encourage infection control practices.

I taught a three hour training session for staff in the evening at every child care centre. Sessions for intervention centres were conducted in March and early April 1996. Sessions for control centres were held in late November 1996. The directors encouraged staff who were unable to attend the session in their own centre to attend on another evening at another centre. I trained intervention centre staff who were not able to attend any evening session, or who joined the centre after March 1996 in a one hour lesson during lunch periods. I presented the training material using a Power Point presentation (Appendix 5), printed on B4 paper and placed in a flip frame mounted to a portable chalk board. I delivered an evaluation form for the training session to all staff to determine if the training was relevant and whether it could be improved. Upon completion of the training session, each carer received a signed individual certificate of training.

I visited the intervention centres every two to three weeks, with a total of 12 visits throughout the 36 weeks. On each visit I went to every child care room and talked with the staff about implementing the intervention. From each visit I identified key issues that became items for a newsletter that I delivered on the next visit (Appendix 6). The newsletter articles addressed questions and concerns that had been raised by staff, and highlighted methods that different centres used to incorporate the infection control principles into daily practice.

Content

The training incorporated "elements of good health training" for child care workers developed by Kendrick [117]:

- "assessment of the audience;
- trainer is familiar with child care and the content is geared to needs;
- convenience;
- professionalism;
- overplanning;
- interactive and experiential activities;
- realistic, practical, concrete information;
- varied activities;
- incentives and rewards; and
- supervisor's and co-workers "buy-in" and attend."

The content of the training was derived from three areas:

1. the Australian guidelines for infection control in child care [56];
2. evidence from other research about spread of infections in children in care; and
3. new techniques I developed in the pilot phase.

From the Australian guidelines were included:

- methods of spread of infectious diseases;
- handwashing technique;

- recommended duration of handwashing by counting to 10 to wash and counting to 10 to rinse;
- frequency of handwashing;
- appropriate use of disinfectants;
- technique of changing a nappy;
- cleaning of bathrooms and potties; and
- washing of toys.

At the beginning of each training session, I discussed the need for infection control in child care and included evidence about excess respiratory and diarrhoeal infections in children who attend child care compared with their peers at home. In addition, I included evidence from research about contamination of the child care environment and how hands spread infectious diseases[54,80,118-,120]. I also discussed child care studies that provide evidence about routines in child care such as the combination of staff functions of nappy changing and food serving [7]. I emphasised the recommended method of washing hands in preference to the use of disposable gloves. Where gloves were to be used, such as for changing soiled nappies, I emphasised timely removal and disposal of the gloves.

The new techniques for the implementation of infection control to child care included:

- use of a small plastic bag that fitted over the child carer's hand like a glove when holding a tissue to wipe a child's nose (the most readily available plastic barrier was the sandwich bag, available at supermarkets);
- use of a bin (colloquially known as a "toy sin bin") to store toys that had been contaminated during the day;
- songs about handwashing to encourage children to take the time to wash thoroughly; and
- use of used computer paper as a disposable barrier on nappy change tables.

I demonstrated the use of a sandwich bag to hold a tissue to wipe the nose on a doll. I then aseptically inverted the bag in the same manner as a glove is removed by peeling back from the wrist. The tissue was then trapped inside the inverted

bag. To facilitate ease of use, I attached the box of sandwich bags to the box of tissues with masking tape. I left one such combination box for trial for every room in the intervention centres. This was the only physical assistance that was provided to the centres. I ensured that carers were aware that children touching their nose could contaminate their hands by modifying a song they commonly use, "put your finger on your nose, that's where your virus grows."

Three songs about handwashing that were developed in the pilot centre were provided in the training sessions. However, I also encouraged the staff to develop their own songs and to share these with other intervention centres through the trial newsletters. A handwashing exercise was undertaken by every staff member during the training session. I demonstrated the effectiveness of good handwashing by using *Glo Germ*, a paste containing particles that fluoresce under ultraviolet light if not removed by washing[121]. I divided the staff into three groups: the first I asked to perform a good handwash as taught; the second I asked to perform a quick handwash as if they were in a hurry and; the third group I asked to wipe their hands with a wet face cloth. I used the wiping of hands as an example as this is a practice frequently performed instead of washing babies' hands. At the end of the washing session I used plain light to illuminate their hands; this showed little difference in the appearance of the hands. I then used an ultraviolet torch to show the particles that had not been removed by inadequate handwashing.

The Australian guidelines recommend using a piece of paper towel on the nappy change mat each time a child has a nappy change[56]. This may prevent contamination of the nappy change mat with faeces from the child, and in reverse may prevent contamination of the child's clothes and skin from organisms on the change mat. However, paper towel was ineffective in this practice because of its small in size and because it was easily torn. I instituted the use of large sheets of computer paper in place of a paper towel. I taught the carers that the change area should always be considered a contaminated area. Only clean toys were allowed to be handed to children in this area, and such toys were to be discarded for

washing either at the end of the change or if they came into contact with the change mat surface.

Outcome

Primary outcome: surveillance of illness

I used the interviews with parents to gather information about illness in children. The parents in this trial provided information about their child for every day. Other child care intervention trials have used information from care givers about child illness. I discounted this method as it could have created an important information bias: the care givers who received the training would have been the source of information about child illness. Also carers could only provide information for the time the child was attending care; they were not aware of illness that may have occurred in evenings or weekends.

After deciding to obtain information about illness from parents, I considered how best to obtain this information. I chose to use the telephone interview in preference to parents' maintaining a diary because diaries demand more time and skill and the participants need motivation to maintain the diary over the time period[122]. The population of parents comprise those who were working in addition to caring for young children, and I considered that this population was likely to be limited with the time they could offer. To maximise the accuracy of recall I chose to have the interviews as close together as possible: every two weeks. I considered recall within this time would be reasonable because illness in young children can have a high impact on parents either through disturbed sleep or the inability of a child to attend child care. Not attending care places a need to either change a parent's work attendance or to make arrangement for alternative care. Because using recall alone may have limited the reports to those illnesses that had a high impact on the family, I provided parents with a calendar for recording illness every day. Parents were to use the calendar as a prompt in interviews. Calendars alone, without the assistance of maintenance in the manner of a diary, have been shown to be an effective aid to recall[122].

I asked the parents to record on the calendar illnesses, medication use and health service utilisation. The records of illnesses were made by the telephone interviewers from Datacol Research every two weeks. The interviewers from Datacol Research used a questionnaire that I developed (Appendix 7). They recorded the parents' responses, and the data were later entered by Datacol Research into a *Dbase* database. Datacol Research checked a sample of 10 per cent of entered data for accuracy. To encourage use of the prompt, the parents were asked if they had the child's calendar in front of them at the beginning of each telephone call. Datacol Research was not informed of the intervention status of the child care centres. The parents were not directly informed of their centre's intervention status, although they may have recognised this from other sources.

In March 1996, I participated in a training evening for interviewers during which the purpose of the trial was outlined, each question was read aloud and discussed and role play interviews were conducted. Datacol Research devised a timetable for interviewers. This ensured that interviewers were rotated throughout the individual evenings to avoid the same interviewer contacting a particular parent every fortnight. They approached the interviews with a philosophy of being "friendly but not familiar". In every third interview, the interviewers ensured that each child attended their centre for at least three days per week, an eligibility criterion.

On the first call, the parents were asked whether one parent was the principal care giver to speak with each week or whether the interviewer should speak with either parent. Parents were asked to elect a day of the week on which they preferred to be telephoned, and they were informed that they would not necessarily speak with the same interviewer each week. From the commencement of the surveillance interviews, parents were telephoned on the same evening of every two weeks. If there was no answer from the parent's phone, the interviewers telephoned every subsequent night until they completed an interview with the parent. Each week the Datacol Research coordinator faxed me with the details of children who had left the trial, parents who were unable to be contacted and children who had been admitted to hospital. Where parents were unable to be contacted, I telephoned the director of the child's centre to seek assistance.

Frequently the parents were on holiday or had moved and had a new telephone number. The Datacol interviewers conducted the interview with these parents as soon as possible after this.

The results reported by parents and recorded by the interviewers for each day were:

1. symptoms of respiratory illness (runny nose, blocked nose and a cough);
2. occurrence of diarrhoea as defined on the calendar (two or more unusually loose or watery bowel motions in a 24 hour period);
3. health service use;
4. medication use; and
5. child and parent absenteeism from care and work.

I classed an occurrence of acute respiratory or diarrhoeal illness as a new episode if it followed three days during which the child had no symptoms. To assess the impact of the intervention on episodes of colds, I used a definition of a cold based on a community intervention trial of virucidal impregnated tissues[105]. A cold was defined as a parent's report of:

- any two of the symptoms of runny nose, blocked nose or cough on any one day, or
- any two of the symptoms of runny nose, blocked nose or cough for two consecutive days, but not including two consecutive days of cough alone.

I did not accept two consecutive days of cough with no other respiratory symptom in the case definition because cough alone was more likely to represent asthma or reactive airways disease than an acute upper respiratory infection. This definition is similar to that used by Wald et al[65] in a longitudinal child care study.

During the third month of surveillance, I validated one measure from the interviews, namely the parent reports of child absenteeism due to illness. I compared these reports with the records maintained at the centres for child attendance. Each reported absence by the parent was also recorded as an absence

by the centre. However, the centre records did not confirm illness; they only recorded absence.

Secondary outcome: implementation of practices

The implementation of recommended infection control practices was recorded by one observer. The observer recorded practices in Table 3.6 for a period of three hours in the mornings in each centre every six weeks using a standard form (Appendix 8). I sought to obtain a measure of duration of handwashing because effective removal of organisms has been shown with handwashes of 15 to 20 seconds duration (Chapter 2). Because the national guidelines recommend a count to 10 to wash and count to 10 to rise, the observer recorded whether a handwash was performed for a count of 20 by counting slowly from one to 20.

The observer was not informed of the content of the training sessions or the intervention status of the centres. In practice the observer became aware of the centre's intervention status over time as she observed differences in behaviour. The staff in the centres were not aware of what the observer was recording during the trial and they were not identified in the records. The centre directors all received the observation records at the end of the trial.

Table 3.6 Infection control practices observed in all centres in each observation period

Handwashing
Whether the child's hands were washed at all before they ate food.
Whether the child's hands were washed as recommended for a count of 20 before they ate food.
Whether the child's hands were washed as recommended for a count of 20 after their own nappy was changed.
Whether the child's hands were washed at all after using a toilet.
Whether the child's hands were washed as recommended for a count of 20 after using a toilet.
Whether staff washed their hands at all after completing a nappy change.
Whether staff washed their hands as recommended for a count of 20 after completing a nappy change.
Nappy change routine
Whether gloves were used when changing a child's nappy.
Whether a paper barrier was placed on the change mat and disposed of after cleaning the child.
Wiping noses
Whether the recommended technique for wiping a nose was used (either protecting the hand with a sandwich bag barrier or handwashing for a count of 20 after a nose wipe).

Other measurements: child risk factors

Because factors concerning a child's health and home life may affect their susceptibility to infectious diseases, I sought to measure these factors in order to enable adjustment as confounders or inclusion as effect modifiers in the analysis. Parents completed a questionnaire about their child's past health and risk factors for illness (Appendix 9). The observer and I delivered the questionnaires to each child care centre and they were sent home with the children. A return envelope, able to be sealed, was provided with each questionnaire. The parents returned the completed questionnaire to their child's centre.

In the questionnaire I asked about aspects of the child's general health including: the parents' rating of the child's health, birth weight, respiratory illness, hospitalisation in the previous 12 months, asthma, presence of tympanostomy tubes; and aspects of the child's home life including the presence of siblings, parental smoking, crowding, parental income and ethnicity. I used a respiratory index score that was devised by Woodward et al [66] to identify children with frequent respiratory symptoms. The score was the sum of each of the respiratory items reported for their frequency in the previous 12 months, with a value of zero to four (Appendix 9 Questions 12 to 25) An additional two points was attained if the child had an episode of pneumonia and an additional two points was attained if a doctor had said the child had asthma.

Other measurements: centre characteristics

The observer and I interviewed the centre directors to collect information about the operation of the centres (Appendix 10). This questionnaire included factors such as: whether the operation of the centre was a private profit-making one or community operated; qualifications of staff; staff to child ratios; and physical aspects of the centre. We asked the directors six months after completion of the trial how many staff were new to their centre in the previous six months.

Analysis

I analysed the data using the computer software *Stata* and *Epi Info* and created graphs using *Excel* [115,123-124].

Primary outcome: illness

Crude rates were calculated for episodes of colds and diarrhoea. I classed the occurrence of a cold or diarrhoea episode as a new episode if it followed three symptom free days. To assess seasonal effects, I plotted the rate of illness for each month of the trial. I examined the crude rates for two age groups and by sex.

I used multivariable modelling in *Stata* to test the impact of the intervention on illness. I used a random-effects Poisson regression model that allowed adjustment for the impact of clustering by child care centre. The random-effects Poisson model in *Stata* uses a generalised estimating equation (GEE) approach. The overall goal of the analysis was to obtain a single overall estimate of the effect of exposure to the intervention after adjusting for potentially confounding factors. To assess the appropriate model I used the strategy proposed by Kleinbaum [125] for logistic regression where the stages are:

1. specification of variables;
2. interaction assessment; and
3. confounding assessment followed by precision.

I applied the multivariable model for all children and for children in two age groups: aged 24 months or under, and over 24 months of age.

Variable specification

I selected potentially confounding variables that could be associated biologically with disease and variables that had been shown in the literature to be associated with illness. The variables were selected from the questionnaire completed by parents. This material provided the initial model. The details of the final models accepted for respiratory and diarrhoeal illness are provided in Chapters 6 and 7.

Adjustment for clustering

Within the GEE framework, I estimated both standard and robust confidence interval estimates. The robust estimate is another measure of variance and is known as "the sandwich estimator of variance" and "Huber and White's estimator". The standard random effects estimates allow the rate to vary by centre. The robust estimator relaxes the assumptions that the model is exact and assumptions about the exact error distribution. Importantly, the robust estimator relaxes the assumption of independence of the observations. The observations for a child in a centre are likely to be similar to another child in the centre, that is clustered by centre. The Robust estimator of variance therefore produces corrected standard errors for correlated observations clustered by centre [126-128].

An example of a command line with a single explanatory variable for intervention status used in *Stata* for Poisson regression for rate of colds was:

```
xtpois coldt status, i(cntrid) ex(covert) robust
```

where

- xtpois was Poisson regression of longitudinal data,
- coldt was the outcome of total number of colds,
- status was the intervention status of the centre the child attended,
- i(cntrid) clustered the analysis by identifier of the centre that the child attended,
- ex(covert) specifies the total number of days the child was exposed as the denominator of the rate, that is enrolled in the trial, and
- robust specifies the robust estimator of variance.

Impact with varying compliance with the intervention

I analysed the impact of the intervention, depending upon compliance with the intervention practices. To grade compliance, I used the observer's record of practices in each centre, a secondary outcome measure. First I graded the intervention centres only into three performance categories. All control centres were graded as 0 for the referent group. Each intervention centre was scored: 1 for poor compliance, 2 for moderate compliance and 3 for good compliance. I compared illness in children from intervention centres with scores 1, 2 and 3 with illness in children from control centres. This maintained an approach to analysis of "intent to treat", whereby all of those intended to be in the intervention group, graded into three groups, were compared with all children in the control group. This analysis addressed the hypothesis that the training intervention reduced the incidence of communicable disease.

There is variability in hygiene standards in centres, and some control centres performed infection control practices better than others. I therefore reanalysed the data with the aim of comparing all centres with good and moderate performance with all centres with poor performance. These analyses used a "treatment received" approach. I established scores for all centres where 0 was the poorest

performance, 1 was a moderate performance and 2 was a good performance. These gradings were made irrespective of their randomised status. I compared illness in children from centres with scores of 1 and 2 with those children in centres with scores of 0. This analysis addressed the hypothesis that good infection control procedures reduced the incidence of communicable disease.

Secondary outcome: implementation of practices

I tabulated and calculated the compliance with each practice that was observed in each centre. I devised four outcome categories for all the events recorded by the observer, as described in Chapter 5. To allow for the impact of clustering, I analysed the observation data using a logistic regression model that adjusted for both time and cluster effect, with the robust estimator of variance, on the four outcome categories. To assess potential bias by the observer I compared the results in the first observation, where the observer was blind to the centre's status, with subsequent observations.

Because ongoing compliance would be crucial to maintain any impact from the intervention, I assessed how the centres performed six months after trial's completion. I compared the performance of the practices six months later in intervention centres with the performance at the end of the trial in intervention centres. I repeated this process for the control group. Many centre directors cited staff turnover as a reason why their centre's performance may have deteriorated over six months. I assessed the impact of staff turnover in intervention centres by analysing separately six months later the performance of those centres with low staff turnover and those with high staff turnover.

Other measurements: child questionnaire

I calculated, for intervention and control groups, the proportion of each of the child's health and home life factors. I performed chi squared tests to determine differences between the two groups.

Pilot Study

Background, 1995

In May 1995, I contacted one centre licensed to care for more than 50 children to seek their assistance in developing and testing a training program. I attended the pilot child care centre during the working days of one week and observed and assisted the staff in their work. I then worked with three of the centre staff to develop infection control methods appropriate for their setting. The child care staff highlighted aspects of child behaviour and routines in child care that they felt affected the implementation of infection control practices. I observed the behaviour of staff and children in the child care rooms. A few examples that show how the transmission of disease was made easy (and what a challenge the implementation of infection control methods was going to be) are as follows:

- children behaved intimately;
- children frequently put object in their mouths;
- children shared toys, some of which appeared to have been contaminated with respiratory secretions and potential faecal organisms by unwashed hands;
- children used the toilet and washed their hands without supervision;
- staff who used gloves when changing nappies left the gloves on to perform other tasks;
- children put toys that had been in contact with the nappy change mat surface into their mouths when having their nappy changed;
- children touched each other's food;
- children sat at meal tables wearing only nappies and no over-clothing;
- children wiped their own noses on their skin or clothing;
- children did not wash their hands after wiping their own nose;
- staff encouraged children to touch their noses in songs;
- staff did not allow enough time for every child to wash their hands before eating;
- staff wiped the noses of numerous children directly after each other; and
- staff did not have the time to wash their hands after wiping a nose and sometimes there was no tap close by.

I discovered that child care workers found washing their hands every time they wiped a nose to be impossible. They stated that they did not have time to get to a tap and wash their hands every time they wiped a nose. These staff preferred barrier methods to protect their hands from contamination with respiratory secretions. Disposable gloves are an obvious useful barrier and they are able to be aseptically removed by peeling back from the wrist over the hand, thereby entrapping the tissue and respiratory secretions within the glove. However, the cost of gloves made them an unacceptable item for the pilot child care centre. Furthermore, there was a risk that gloves on hands would not be removed after wiping a nose, thereby creating another vehicle for the spread of organisms. I identified an alternative barrier as small plastic sandwich bags, used to cover the carer's hand while using a tissue. The bags could be inverted for aseptic removal in the manner of gloves, yet unlike gloves they would not be left on to perform other tasks.

The staff in the pilot centre nursery, the room for the care of children from birth to 18 months of age, cared for 10 babies. They were able to reduce the children's contact with particular toys to no more than four hours per day. This limited the potential of acquiring infection from this fomite. They instituted rotation of morning and afternoon toys, and the toys were washed at the end of each four hour session and were hung to dry. The staff were also able to remove from general availability a toy that had been extensively played with by a symptomatic child. These "interrupted toys" were washed with the other toys at the end of the session.

Process testing, 1996

In February 1996, I conducted the pilot program to test:

1. the process of recruitment of parents;
2. the telephone surveillance process and questions;
3. the training materials; and
4. the recording of observations of infection control practices.

Recruitment of parents and children

To recruit parents in the pilot study, I visited the centre early in the morning and late in the afternoon. I recruited thirty parents to participate. It was apparent that this method of recruitment was time consuming and would have failed to attain the sample required for the trial. I determined that to obtain the large number of children and parents required for the trial itself, I would need to seek the assistance from the centre directors and staff.

Telephone surveillance

Thirty parents from the pilot centre and another five parents who were epidemiology researchers participated in pilot testing of the telephone surveillance of illness. I elected to use this latter group of parents to gain feedback on the performance of the interviewers. One parent highlighted a difficulty arising from the interviewer's only speaking to the person whose name was on the enrolment form and not identifying the purpose of their call. I was able to address this difficulty in the recruitment process for the trial by including the names of both parents or home guardians on the enrolment form. I also ensured that interviewers always stated they were calling for "The Child Care Communicable Diseases Trial". Two telephone interviews were conducted with each parent. The telephone interviews were conducted without difficulty with the parents from the pilot centre. The time for each interview was between two and five minutes. Following the pilot, we altered the order of the questions. The parents used the calendars successfully and did not suggest any changes to the format.

Training materials

The content of the training is discussed earlier in this chapter. I presented the training program to all the staff in the pilot centre and sought their written and verbal feedback. They were enthusiastic about the content and presentation of the training, in particular the handwashing exercise. It was clear that although I had spent time in the pilot centre explaining the pilot and the trial to staff, they still had many questions about the trial itself and they requested written information.

During the day they were not able to consider or ask questions. For the trial I developed an information booklet and left copies of this booklet in each child care room and staff room in every enrolled centre.

Observation of implementation of the intervention

In the pilot centre I designed a form for the observer to use in the trial (Appendix 8). I trained the observer in two three hour sessions in the pilot centre. In the second session, both the observer and myself recorded the observations to compare variability. There was only one difference concerning one child's washing their hands, in the 58 recordings. I selected an observer who had not been trained in child care, infection control or infectious diseases to minimise observer bias in favour of how the methods should have been performed. I also sought personality attributes in the observer, including meticulous writing and recording, and affable demeanour to enable acceptance by child care staff. The observer was not informed of the content of the training session.

Discussion

The design of this study overcomes the limitations inherent in some of the earlier studies. This design allows for the impact of clustering as some have not previously done: the sample size allowed for the impact of the clustered design and the analyses adjusted for clustering by centre. The design separated the source of the surveillance data from those who received the intervention. Parents reported illness in this trial where in other studies the child care staff reported illness. There is clear bias when the child care staff, who attended the training, report whether children in their care suffer from illness. Furthermore reporting by staff may not give a complete picture of illness as it is limited to only the days the child attends care and illness in weekends and evenings is not detected. Some have relied upon parents informing staff about children's illness whilst they have not been in care but this is a naive expectation. Parents are not likely to report a history of illness to the child care staff because it places their child at higher likelihood of being excluded from the centre. Reporting by staff is also likely to give higher rates of disease in younger children. Because staff with older children have a larger number of children in their care, they are less likely to detect illness than those caring for younger children.

However, the study design does include some limitations. The parents may not have been blind to the intervention status of their centre. Although parents were not directly informed of their centre's intervention status, they may have recognised this status from other sources. This lack of blinding may have led to bias in parent reporting. Parents who believed that their children were in a control centre may have been more likely to report illness either unknowingly or knowingly if they believed that their centre's hygiene was inadequate. Similarly, parents of children in intervention centres may have reported less illness if they thought that their centre was performing new infection control procedures. On the other hand, intervention centre parents may have heightened awareness of illness in their children and knowledge of their centres practices may have increased their reports of illness. It would have been impossible to institute changes in intervention centres without potential detection by parents, because

parents enter the child care rooms at least twice each day when they deliver and collect their children. The age of the children, being too young to leave without supervision, and the legislative requirement that parents sign when leaving and collecting their children, ensure considerable contact with the centre and staff every day. Parent reporting may also have been affected by recall: their memory of illness may have been biased towards illness that required absence from child care. This could have occurred in cases where illness in young children had a high impact on parents because of work commitments.

In the process of the recruitment of children, the care givers passed the enrolment letters onto the parents in the centre. This may have introduced a bias whereby the child care staff approached only selected parents. I asked directors and staff to hand the enrolment forms to parents of all eligible children, but I have no measure of whether they followed this process. However, without the assistance of the centre staff I would not have been able to recruit the required sample within the available time frame.

The recording of the compliance with infection control practices could have been prone to bias on the part of the observer. Alternatively children and staff may have changed their behaviour when she was present. I considered that children were not likely to change their behaviour to impress the observer, and that staff routines were established and speedy and could not be quickly altered to impress an observer. In the pilot phase I noted that staff, whilst aware of my presence with the observer, did not necessarily institute the practices I had taught them.

Using the city of Canberra to study the effects of the intervention may have introduced other limitations. Child care centres in the ACT are probably similar to those in other areas of Australia, but their clientele is most likely not representative of the Australian child care population. Families in the ACT are frequently two income and affluent. Also I recognised that because Canberra is a small city, child care workers from intervention centres would have contact with workers from control centres, introducing the risk of contamination in control centres. I attempted to prevent this by education of the child care directors and

staff, and to measure any contamination by having the observer record infection control practices in all centres throughout the trial.

Chapter 4 Results: The Centres and the Cohort

Overview

In this chapter, I present the results of recruitment of child care centres, as well as the number of staff who attended training and children who enrolled in the trial. Furthermore I describe the dynamics of the cohort with participant flow and attrition. The characteristics of the intervention and control children's health and home life are compared from the information provided by the questionnaire completed by parents. Finally, I present an assessment of generalisability by comparing details from the parent questionnaire data with data from the Australian Bureau of Statistics Child Care Survey collected in the same year.

Child care centres

Twenty-seven long day care centres were licensed in the ACT to care for 50 or more children as at 1 February 1996. All of these centres cared for children in age-segregated rooms. One of the 27 centres was the pilot centre. The recruitment rate for child care centres was 88 per cent (23/26). Three centre directors declined the invitation to participate in the trial. They explained their refusal in the following terms:

1. the staff were already busy preparing for government accreditation;
2. the staff would not attend a training evening without being paid, and the centre did not have the required money; and
3. the director was not able to present the proposal to the parent management committee within the next month.

Following randomisation there were 11 intervention and 12 control centres. Sixteen of the centres were commercially operated (eight intervention and eight control centres). The remainder were community operated, non-profit centres (three intervention and four control centres). There was no difference between the proportion of staff with any qualification in child care in the intervention and control centres (59/125, 58/110 respectively; chi-square test p value = 0.4). In all centres, children were separated by age into different care rooms with a range of between three and five rooms per centre (Table 4.1). Centres had more children registered as attendees than they had licensed number of positions because in many cases more than one child shared a full time position. Staff to child ratios, regulated by the government, ranged from one to five for care of babies, to one to 12 for care of preschool children. One centre, control centre number 12, ceased operation in July 1996.

Table 4.1 Number of licensed child positions, enrolled children and child care rooms for 12 control and 11 intervention centres

	Intervention			Control		
Centre	Licensed child positions	Enrolled children	Number of care rooms	Licensed child positions	Enrolled children	Number of care rooms
1	69	60	3	57	101	3
2	62	82	3	77	116	4
3	57	73	3	67	75	4
4	68	67	3	82	64	3
5	85	92	4	55	82	3
6	77	74	5	80	92	4
7	75	140	4	62	77	4
8	84	91	4	84	60	4
9	56	56	4	76	104	3
10	55	70	3	75	110	4
11	74	70	4	57	62	4
12	-	-	-	50	24	2
Total	762	875		822	967	

Staff training

I conducted training sessions on weekday evenings in all 23 centres. In one centre the three hour training session was split over two evenings. A total of 324 staff members attended the training. There were 175 staff from intervention centres, and 149 staff from control centres, who attended training. One hour daytime training was provided at three intervention centres where staff could not attend the evening sessions: six staff attended these sessions. The directors of 10 of the 11 intervention centres attended the training evening. The directors of all the control centres attended the training.

Participant flow and follow up

Recruitment of children

Children were eligible to enrol in the trial if they attended one of the 23 centres for at least three days each week and if they were under four years of age at 1 January 1997.

Parents of 661 children completed enrolment forms, however 70 children did not meet the eligibility criteria for the trial. A further 24 children were removed from the analysis leaving a total of 558 children included in the study (Figure 4.1). Of these remaining children, 469 (84 per cent) were enrolled at the beginning of the trial and 89 (16 per cent) were recruited between April and September 1997. The final sample attained was 113,677 child days of observation.

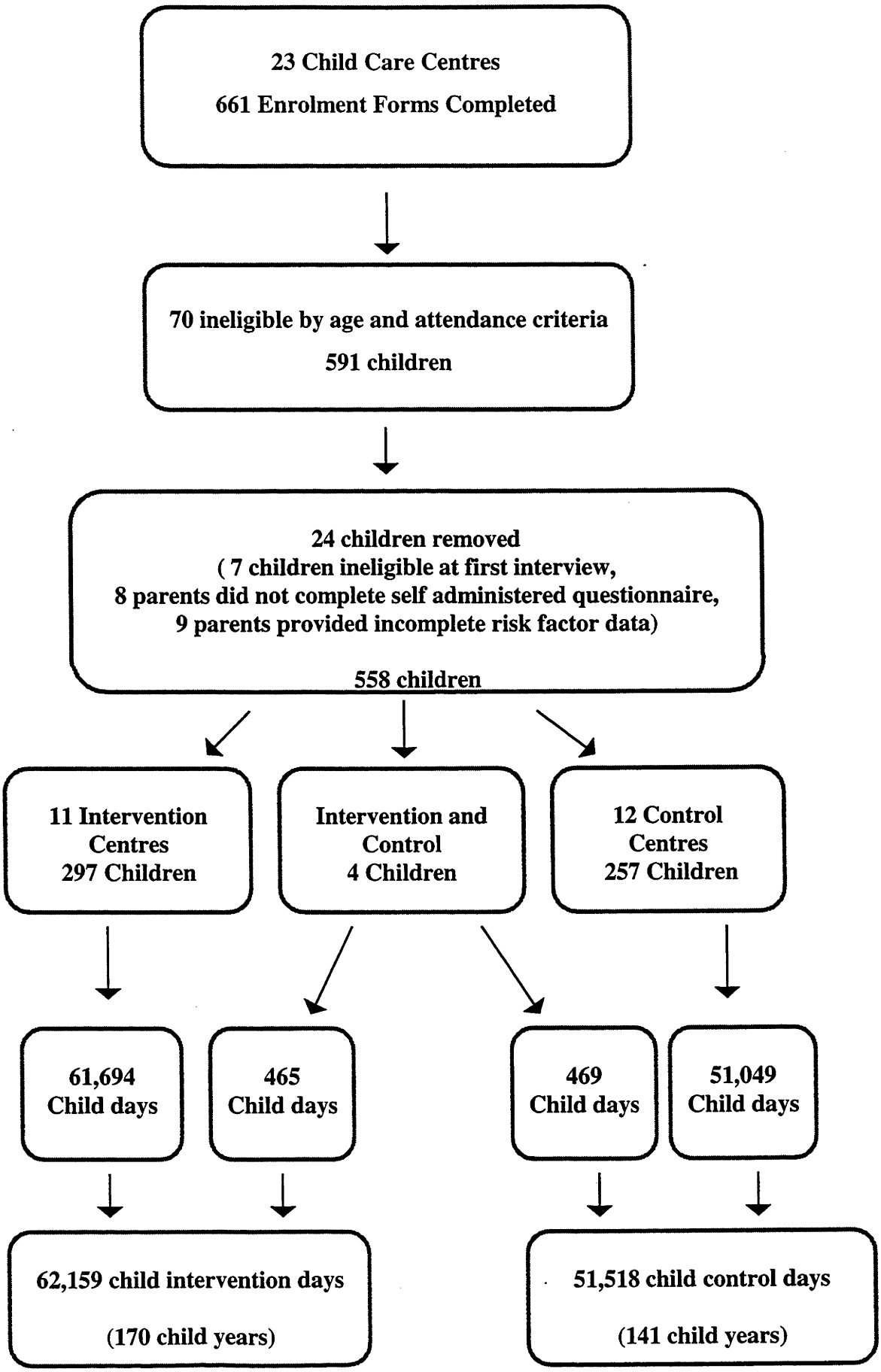
Migration

Six children moved from one enrolled centre to another and continued to participate in the trial: two of these moved to a centre with the same intervention status, two moved from a control to an intervention centre, and two moved from an intervention to a control centre (Figure 4.1).

Surveillance of illness

Surveillance of illness was carried out for 254 days. The parent interview telephone calls commenced on 7 March 1996 and continued until 16 November 1996. Recorded absences because of illness in the first two weeks of May 1996, were validated with centre records of attendance. In this period, Datacol recorded 268 absences, 136 in intervention centres and 132 in control centres, all reported absences were also recorded in child care centre attendance records.

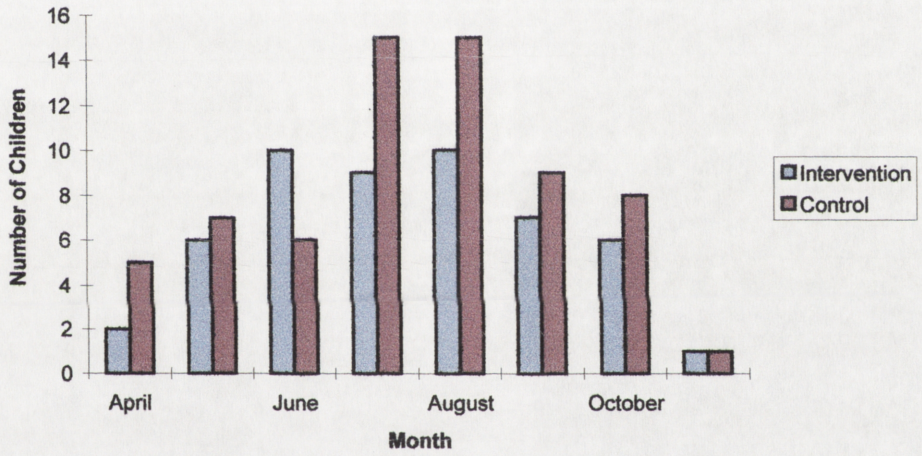
Figure 4.1 The cohort of children, recruitment and observation period



Attrition

The number of children who left the trial was 123 (22 per cent), most of these children left the trial between June and October 1997 (Figure 4.2). The drop out rate was lower in intervention centres than in control centres (51/220 (17 per cent) intervention, 72/259 (28 per cent) control, chi-square test p value = 0.002).

Figure 4.2 Children leaving the trial by month and intervention status



The reason for the high dropout rate was primarily twofold; children could not participate because they left the enrolled centre, or they became ineligible to participate because they decreased their days of care to less than three days per week (Table 4.2). Only five parents (of seven children) refused to continue to participate in the trial and they cited the following reasons:

- marital split (1);
- child moved to live with another parent (1);
- too busy to continue (2); and
- a crisis in the family (1).

Table 4.2 Reason for leaving the trial provided by parents of 123 children

Reason	Number	Per cent
Child left the centre	79	64
Reduced days attending centre	25	20
Parent of child elected not to continue	7	6
Unknown	12	10
Total	123	100

Child care directors reported that the high turnover of children in child care centres was a normal occurrence. Common reasons cited by the directors for this turnover were that: parents sought care in a more convenient location, or a parent stayed home to care for a child when a sibling was born or a parent changed their employment. Of the 79 parents who removed their child from an enrolled centre, I obtained the reasons for the departure of 36 children (Table 4.3).

Table 4.3 Reason provided by 79 parents who removed their child from an enrolled centre

Reason	Number	Per cent
Family moved	17	22
Child attends another centre, family day care or home care by a parent	11	14
Parent work redundant	3	4
Centre closed	5	6
Ill health	1	1
Unknown	42	53
Total	79	100

Participation rate

It was not possible to determine accurately the number of children at each centre who were eligible to participate in the trial. The denominator for this rate would be all children who fulfilled the eligibility criteria. To provide this information either the staff or I had to identify every child under four years of age who attended three days per week at the beginning of the year. The child care workers were not willing to perform this task and I was unable to read the records at each centre. At the time, the staff were assisting recruitment by distributing information sheets and enrolment forms to all parents, and I elected not to pursue their further assistance in determining the number of eligible children. To establish a conservative estimate of the participation rate, I used the number of licensed child positions in the younger (non-preschool) rooms of the centres as the denominator. The total number of licensed child positions excluding the preschool rooms was 959 (Table 4.4). The enrolment of 558 children therefore represents a potential participation rate of 59 per cent (558/939). This represents a potential 67 per cent participation rate in intervention centres (297/441) and 52 per cent potential participation rate in control centres (259/498). These estimates are conservative as not every licensed position represents a child who fulfilled the eligibility criteria of three days per week attendance.

Non participants

I attempted to obtain minimal non-identified information about children who were not participating in the trial. However, this required more cooperation from the child care staff than was attainable.

Table 4.4 Number of licensed positions in intervention and control centres, excluding preschool room positions

	Intervention	Control
Centre	Licensed positions excluding preschool room	Licensed positions excluding preschool room
1	36	35
2	35	50
3	35	45
4	36	48
5	59	33
6	42	47
7	40	40
8	46	62
9	40	40
10	25	45
11	47	38
12	-	15
Total	441	498

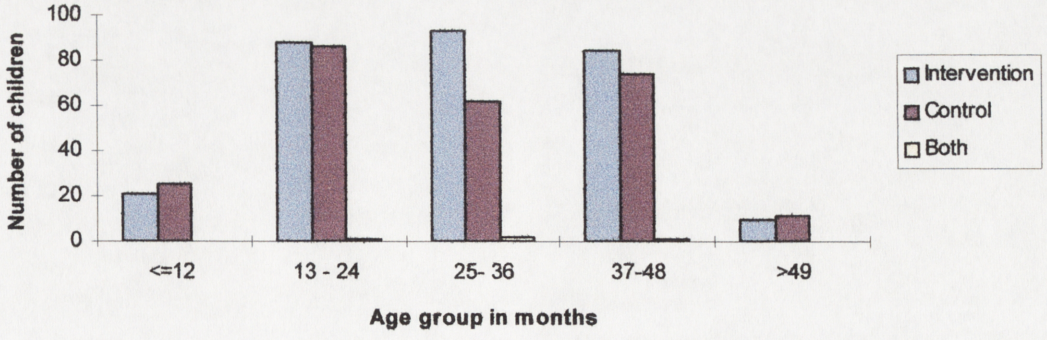
Comparison of intervention and control centre children

Distribution of children by centre, age and sex

More children were recruited from intervention centres (297, 53 per cent) than from control centres (257, 46 per cent). The mean number of children per centre was 28.4 from intervention centres and 22.8 from intervention centres.

Some of the children enrolled in the trial were born after the trial commenced. One child was born after the trial had reached its midpoint. The age of the children at the middle of the trial, 30 June 1996, ranged from 2 months before birth to 60 months after birth. Approximately one third of children were from each of the ages of one, two and three years, being 31, 28 and 28 per cent of the cohort respectively (Figure 4.3).The sex distribution was equal: 50 per cent female in the intervention group and 51 per cent female in the control group (148/296 intervention, 128/258 control, chi square test p value = 0.7).

Figure 4.3 Age group of 558 children (age in middle of the trial) by intervention status



Child health characteristics

Most of the children in the trial were reported by their parents to be in good health, were born with a weight over 2,500 g and had been breast fed at some time (Table 4.5). A large proportion of children had been breast fed (93 to 95 per cent); however, less than half had been predominantly breast fed for six months (46 to 48 per cent). This figure was not different by intervention status. The only difference between the health variable of intervention and control children was the parents report of whether their child had had chickenpox.

Table 4.5 Health characteristics for 554 children in intervention and control centres*

	Intervention n= 296			Control n= 258			p value†
	n	%	unknown	n	%	unknown	
Child health good to excellent	274	93	2	240	93	0	0.9
Weight at birth: <1,500 g	4	1	0	0	0	0	
1,500-2,500 g	27	9	0	22	9	0	
over 2,500 g	265	90	0	236	91	0	0.2
More that 2 weeks preterm	56	19	0	37	14	0	0.2
Ever breast fed	276	93	0	244	95	0	0.5
Predominantly breast fed for 6 months	136	46	0	125	48	0	0.5
Smoking during pregnancy	42	14	0	27	11	0	0.2
Grommets in place	15	5	0	10	4	0	0.5
Doctor said child had asthma	71	24	0	52	20	0	0.3
Regular medication prescribed	34	12	2	38	15	2	0.7
Regular homeopathic medication	11	4	1	16	6	1	0.4
Parent reported "frequently or constantly" in previous year:							
cold	50	17	0	36	14	1	0.4
cough	33	11	0	24	9	0	0.5
hayfever	2	1	0	2	1	0	0.9
wheeze	11	4	0	17	7	0	0.1
tonsillitis	4	1	0	3	1	0	1.0
thick nasal discharge	36	12	0	23	9	0	0.3
sore throat	11	4	0	10	4	0	0.9
earache	25	8	0	23	9	0	0.9
middle ear infection	28	9	0	22	9	0	0.7
Pneumonia (1 or more episodes in previous year)	9	3	0	9	4	0	0.8
Bronchitis (2 or more episodes in previous year)	6	2	0	12	5	0	0.1
Discharging ear (more than 2 episodes in previous year)	12	4	0	16	0	6	0.3
Respiratory Score > = 18‡	133	44	0	116	45	0	1.0
Has had chicken pox	103	35	0	68	26	0	0.03
Ever hospitalised	71	23	2	62	24	0	0.9

* The total cohort was 558 children; the four children who attended both intervention and control centres are not represented in this table

† Chi square test or Fisher's exact test

‡ As calculated by Woodward et al[66] (Chapter 2 Methods)

The apparently significant association between a history of chicken pox and centre status (Table 4.5) is due to effect modification: the crude relative risk of having had chicken pox if the child was new to care was 0.44 (p value <0.001), in the intervention group this was 0.15 (p value <0.001) and control group 0.61 (p = 0.05). That is, the significant difference in terms of a history of chicken pox between intervention and control centre children is likely to be due to more children in control centres being new to child care (Table 4.6, below).

Child care history

More children in control centres had commenced child care in the six months prior to the trial than had children in intervention centres, and this difference was of borderline statistical significance (Table 4.6). More of the children from intervention centres had attended child care for the first time when they were less than six months of age, however this was not statistically significant.

Table 4.6 Child care history of 554 children in intervention and control centres*

	Intervention n= 296			Control n= 258			p value†
	n	%	Unknown	n	%	Unknown	
First attended care under 6 months of age	47	**16**	0	31	**12**	0	0.2
Attended another form of care	13	**4**	0	15	**6**	0	0.4
New to child care in previous 6 months	68	**23**	0	77	**30**	0	0.06

* The total cohort was 558 children; the four children who attended both intervention and control centres are not represented in this table
† Chi square test

Home environment

The children in the trial were predominantly from families with a high income, over 75 per cent of these families had an income in excess of $50,000. Government assistance for child care fees, "fee relief", is means tested and depends upon the combined family income and the number of children who are attending care. One third of families received this fee assistance. Families predominantly spoke English at home. Most children were from a two parent household and crowding, defined as more than one child per bedroom, was rare. One quarter of households had an adult who was a smoker living in the home, but only 12 to 13 per cent claimed that someone smoked inside the home. No significant difference was found between the home environment of children in intervention centres and those in control centres (Table 4.7).

Table 4.7 Home and family characteristics of 554 children in intervention and control centres*

	Intervention n= 296			Control n= 258			p value†
	n	%	unknown	n	%	unknown	
Language other than English at home	9	3	0	9	4	0	0.8
Animals in the home	128	43	0	112	43	0	0.9
Adult who lives in home smokes	73	25	0	62	24	0	0.8
Smoking inside the home	39	13	0	30	12	0	0.6
Single parent household	28	10	0	26	10	1	0.8
Parent age > 35	192	65	0	161	63	0	0.6
Mother completed questionnaire	249	84	0	229	88	0	0.1
Income:							
Over $ 50,000	213	77	20	178	75	20	0.4
Less than $ 15,000	5	2	20	8	4	20	0.3
Means tested government assistance for child care costs (fee relief)	100	34	4	78	33	18	0.6
More than 4 people live in the home	42	14	0	24	9	0	0.08
Crowding (more than 1 child per bedroom)	19	6	0	13	5	0	0.5
Electric heating	172	58	0	146	57	0	0.8
Gas heating	172	58	0	148	57	0	0.7
Wood heating	33	11	0	31	12	0	0.7
Sibling in school	90	30	0	74	29	0	0.7
Sibling in care	111	38	0	105	41	0	0.4

* The total cohort is 558 children; the four children who attended both intervention and control centres are not represented in this table
† Chi square test

Generalisability

In March 1996, the Australian Bureau of Statistics (ABS) conducted a child care survey throughout Australia. Three features of the ABS survey can be compared with the trial cohort (Table 4.8): the families in the cohort of this study had a higher income than their Australia-wide counterparts; there was a smaller proportion of families in this study who were single parents; and there was a smaller proportion of families in this study who spoke a language other than English at home compared with families of child care attendees across Australia.

Table 4.8 Comparison of home characteristics of the cohort with child care attendees across Australia

	Per cent attending child care in Australia	Per cent in trial cohort
High income*	32	70
Low income†	17	2
Single parent home	19	10
Language other than English spoken at home	8	3

* ABS > $51,948 per annum, cohort > $50,000 per annum

† ABS < $20,800 per annum, cohort < $20,000 per annum

Discussion

The final sample of 311 child years was below the target sample size of 398 child years. The smaller than targeted sample size could have led to a lack of power to be able to detect significant changes in illness, but this was not the case in the results (Chapters 6 and 7). Child care positions that were shared between part time children accounted for some of this shortfall. I had not anticipated a large number of part time children attending long day care centres. At the planning stage of the trial in early 1995, I telephoned a sample of 15 long day care centres and found part time attendance was uncommon: 13 of these only accepted children in full time positions. In the period from this planning stage the commencement of the trial, the practice of accepting part time children appeared to have changed because of economic need.

Attrition also contributed to a sample size that was smaller than the target. I had anticipated that there would be some movement of children out of centres over the study period and thus a loss of children from the cohort. Because of this I facilitated recruitment of children from March until the end of September 1996. However, replacement of children who left the trial was not sufficient: from June to October, 101 children left the trial and only 45 new children were recruited. Centre directors were not able to fill vacant child care positions, partly because of a downturn in employment in the city at the time. The closure of one centre during the trial, and two centres six months later, because of lack of economic viability highlighted this problem. When employment decreased through voluntary redundancies offered by the Commonwealth Government, the principal employer in the city, the need for child care decreased. Being unable to recruit new children for the trial because the child care positions were not able to be filled was not anticipated.

The characteristics of the intervention and control children's health and home life are similar in many respects. However, with a small sample randomisation may not have distributed potential confounders and risk factors, measured and

unmeasured, evenly among the two groups. Certainly one potentially important difference between the two groups was the higher number of children in control centres who were new to child care. Being new to care has been cited as a risk factor for infections [8,14,15,129]. This issue is addressed in the analysis.

Chapter 5 Results: Implementation of the Intervention

Overview

The purpose of the observations in all centres during the trial was twofold: firstly, to determine whether the intervention centre staff implemented the practices that were taught in the training sessions; secondly, to determine whether these techniques were introduced into the control centres by staff who may have become aware of the methods through work and other contact with intervention centre staff. The tables in this chapter represent aggregated scores for performance in intervention group and control group for each observation period. In testing for difference in performance between the two groups, each individual centre's score for each observation was used in a regression analysis to adjust for the clustering effect of each centre and time of observation. Training of staff resulted in performance of recommended infection control techniques in intervention centres during the trial and adherence to these techniques was consistently higher than in control centres.

The observer returned to the centres six months after the trial was completed, that is six months after the control centre staff had been trained. The purpose of this series of observations was to determine whether intervention centre staff had managed to maintain their standards of practice and whether infection control practices had improved after only one training session for control staff. Intervention centre standards fell after six months but remained well above the level of control performance during the trial. The fall in standards is likely to be partly due to staff turnover. Control centre standards improved after training and in some practices attained the same performance as in intervention centres.

Completed observations

The observer recorded infection control practices in each of the 23 centres enrolled in the trial. There were six observation episodes in 20 centres, five episodes in two centres that joined the trial after the first set of observations, and four episodes in one centre that closed during the trial. Thus there was a total of 134 observation episodes during the trial. Six months later the observer recorded observed practices for one episode in each of 21 centres, two centres having ceased operations by that time.

The same observer completed all observations. The observer was not informed of the intervention status of each centre nor of the content of the training sessions. Each observation episode was of three hours duration between the hours of 9 am and 12 noon. The observer recorded performance of the infection control practices listed in Chapter 3 Methods (Table 3.6).

Crude proportions

All observed practices

Handwashing

Children eating and toileting

Children's washing of their hands was consistently better performed in intervention centres than in control centres, with an aggregated performance of recommended handwashing in intervention centres from 62 per cent after toileting to 78 per cent before eating (Table 5.1c). In control centres, recommended handwashing for children did not exceed 23 per cent. Children's handwashing after toileting is frequently an independent child activity. Any attempt to wash hands after toileting was 80 per cent or higher in intervention centres during the trial (Table 5.1a, 5.1b). However, in control centres the proportion was sometimes low. In the 5th observation, in only 45 per cent of occasions did children attempt to wash their hands after toileting. This

observation took place in late winter and early spring, when the weather in the city is very cold.

Children after nappy changes

I hypothesised that after nappy changes, it would be easier for staff to wash toddlers' hands than babies' hands because toddlers were able to stand. There was a difference between toddler and baby handwashing in intervention centres at the first observation; however, this was not present in observations two to six (Table 5.1a, 5.1b). The intervention centre staff developed approaches to washing babies hands over time. Overall, approximately 70 per cent of babies and toddlers had their hands washed as recommended after a nappy change (Table 5.1c). In control centres, no babies had their hands washed after a nappy change and 10 per cent or less of toddlers washed their hands after a nappy change.

Staff after nappy changes

Child care staff were clearly aware of the need to wash their own hands after a nappy change. Control centre staff performed a handwash at all over 84 per cent of occasions; however, the recommended duration of handwash was only performed between one and five per cent of occasions (Table 5.1a, 5.1b). In intervention centres, staff performed any handwash over 92 per cent of the time that they changed nappies and they attained a recommended handwash between 54 and 82 per cent of occasions (Table 5.1a, 5.1b).

Table 5.1a Handwashing in intervention and control centres for six observation episodes March to November 1996

	Observation 1						Observation 2						Observation 3					
	Autumn						Autumn						Autumn/ Winter					
	Intervention			*Control*			Intervention			*Control*			Intervention			*Control*		
	n	total	%	*n*	*total*	*%*	n	total	%	*n*	*total*	*%*	n	total	%	*n*	*total*	*%*
Children																		
Before eating																		
Any wash	303	310	**98**	*279*	*279*	***100***	443	486	**91**	*320*	*416*	***77***	529	597	**89**	*510*	*658*	***78***
Recommended	272	310	**88**	*76*	*279*	***27***	384	486	**87**	*112*	*416*	***27***	459	597	**77**	*125*	*658*	***19***
After nappy change recommended wash																		
Babies	7	24	**29**	*0*	*12*	***0***	58	75	**77**	*0*	*60*	***0***	42	69	**61**	*0*	*42*	***0***
Toddlers	46	71	**65**	*5*	*125*	***4***	59	86	**69**	*10*	*104*	***10***	87	125	**70**	*8*	*123*	***7***
All ages	53	95	**56**	*5*	*137*	***4***	117	161	**73**	*10*	*164*	***6***	129	194	**66**	*8*	*165*	***5***
After toileting																		
Any wash	106	114	**93**	*83*	*88*	***94***	141	167	**84**	*80*	*114*	***70***	133	150	**89**	*97*	*162*	***60***
Recommended	72	114	**63**	*29*	*88*	***33***	108	167	**65**	*14*	*114*	***12***	102	150	**68**	*22*	*162*	***14***
Staff																		
After nappy change																		
Any wash	124	134	**93**	*162*	*164*	***99***	192	195	**98**	*200*	*227*	***88***	215	234	**92**	*194*	*211*	***92***
Recommended	73	134	**54**	*4*	*164*	***2***	147	195	**75**	*6*	*227*	***3***	157	234	**67**	*6*	*211*	***3***

Table 5.1b Handwashing in intervention and control centres for six observation episodes March to November 1996

	Observation 4						Observation 5						Observation 6					
	Winter						**Winter/ Spring**						**Spring**					
	Intervention			*Control*			Intervention			*Control*			Intervention			*Control*		
	n	total	%	*n*	*total*	*%*	n	total	%	*n*	*total*	*%*	n	total	%	*n*	*total*	*%*
Children																		
Before eating																		
Any wash	596	682	**87**	*573*	*748*	***77***	606	675	**90**	*580*	*788*	***74***	711	739	**96**	*626*	*828*	***76***
Recommended	515	682	**76**	*158*	*748*	***21***	533	675	**79**	*151*	*788*	***19***	552	739	**75**	*237*	*828*	***29***
After nappy change recommended wash																		
Babies	48	67	**72**	*0*	*68*	***0***	67	89	**75**	*0*	*75*	***0***	53	80	**66**	*0*	*72*	***0***
Toddlers	77	113	**68**	*9*	*122*	***7***	82	106	**77**	*10*	*109*	***9***	75	109	**69**	*14*	*134*	***10***
All ages	125	180	**69**	*9*	*190*	***5***	149	195	**76**	*10*	*184*	***5***	128	189	**68**	*14*	*206*	***7***
After toileting																		
Any wash	154	184	**84**	*98*	*173*	***57***	161	191	**84**	*64*	*143*	***45***	183	230	**80**	*102*	*186*	***55***
Recommended	115	184	**63**	*29*	*173*	***17***	118	191	**62**	*13*	*143*	***9***	127	230	**55**	*20*	*186*	***11***
Staff																		
After nappy change																		
Any wash	211	215	**98**	199	222	**90**	227	229	**99**	*191*	*227*	***84***	203	208	**98**	*199*	*226*	***88***
Recommended	142	215	**66**	3	222	**1**	187	229	**82**	*12*	*227*	***5***	159	208	**76**	*8*	*226*	***4***

Table 5.1c Handwashing in intervention and control centres for six observation episodes March to November 1996

	All Observations					
	Intervention			Control		
	n	total	%	n	total	%
Children						
Before eating						
Any wash	3188	3489	**91**	*2888*	*3717*	***78***
Recommended	2715	3489	**78**	*859*	*3717*	***23***
After nappy change recommended wash						
Babies	275	404	**68**	*0*	*329*	***0***
Toddlers	426	610	**70**	*56*	*717*	***8***
All ages	701	1014	**69**	*56*	*1046*	***5***
After toileting						
Any wash	878	1036	**85**	*524*	*866*	***61***
Recommended	642	1036	**62**	*127*	*866*	***15***
Staff						
After nappy change						
Any wash	1172	1215	**96**	*1145*	*1277*	***90***
Recommended	865	1215	**71**	*39*	*1277*	***3***

Nappy change procedure

Using a paper barrier on the nappy change table was consistently performed better in intervention centres than in control centres, with a range of 82 to 92 per cent in intervention and 26 to 37 per cent in control centres (Table 5.2a, 5.2b). Glove use was lower in intervention centres than in control centres: 28 per cent intervention, 37 per cent control (Table 5.2c). Glove use was not encouraged in the intervention training. There was little difference between the two groups as to whether they removed the glove as soon as they had cleaned a child. On approximately 40 per cent of occasions, gloves were left on after a child was cleaned, for instance when staff picked up a child's clothing to dress the child (Table 5.2c).

Nose wiping method

Staff in intervention centres readily adhered to the recommended technique for wiping a nose. The most popular method used was a sandwich bag over the carer's hand when holding a tissue. The observer recorded that a nose wipe met the recommended practice if the carer used a sandwich bag or disposable glove over their hand or if the carer washed their hands for a count of 20 after wiping a child's nose. Adherence to hygienic nose wiping in intervention centres was high throughout the entire trial. In the early observation periods staff in control centres made attempts at infection control methods when wiping a child's nose (Table 5. 2a). However, the recommended hygienic approach to wiping a nose was rarely performed in control centres over the entire trial (Table 5.2c).

Table 5.2a Nappy change procedure and nose wiping in intervention and control centres for six observation periods March to November 1996

	Observation 1						Observation 2						Observation 3					
	Autumn						Autumn						Autumn/ Winter					
	Intervention			*Control*			Intervention			*Control*			Intervention			*Control*		
	n	total	%	*n*	*total*	*%*	n	total	%	*n*	*total*	*%*	n	total	%	*n*	*total*	*%*
Nappy changes																		
Disposable barrier on mat	123	133	**92**	*55*	*137*	***40***	164	195	**84**	*47*	*180*	***26***	215	234	**92**	*53*	*158*	***34***
Gloves used	44	133	**33**	*61*	*137*	***45***	53	195	**27**	*92*	*180*	***51***	69	234	**29**	*60*	*158*	***38***
Remove gloves as recommended	26	44	**59**	*30*	*61*	***49***	41	53	**77**	*49*	*92*	***53***	53	69	**77**	*48*	*60*	***80***
Nose wiping procedure																		
Recommended nose wipe	78	79	**99**	*1*	*55*	***2***	87	94	**93**	*4*	*53*	***8***	83	84	**99**	*4*	*80*	***5***

Table 5.2b Nappy change procedure and nose wiping in intervention and control centres for six observation periods March to November 1996

	Observation 4						Observation 5						Observation 6					
	Autumn						Autumn						Autumn/ Winter					
	Intervention			*Control*			Intervention			*Control*			Intervention			*Control*		
	n	total	%	*n*	*total*	*%*	n	total	%	*n*	*total*	*%*	n	total	%	*n*	*total*	*%*
Nappy changes																		
Disposable barrier on mat	176	215	**82**	*65*	*222*	***29***	201	229	**88**	*74*	*227*	***33***	175	208	**84**	*86*	*232*	***37***
Gloves used	63	215	**29**	*91*	*222*	***41***	65	229	**28**	*63*	*227*	***28***	44	208	**21**	*58*	*226*	***26***
Remove gloves as recommended	35	63	**56**	*54*	*91*	***59***	38	65	**58**	*45*	*63*	***75***	29	44	**66**	*29*	*58*	***50***
Nose wiping procedure																		
Recommended nose wipe	88	92	**96**	*5*	*85*	***6***	90	90	**100**	*16*	*76*	***21***	65	66	**98**	*9*	*58*	***16***

Table 5.2c Nappy change procedure and nose wiping in intervention and control centres for six observation periods March to November 1996

	All Observations					
	Intervention			*Control*		
	n	total	%	*n*	*total*	*%*
Nappy changes						
Disposable barrier on mat	1054	1214	**87**	*380*	*1156*	***33***
Gloves used	338	1214	**28**	*425*	*1150*	***37***
Remove gloves as recommended	222	338	**66**	*255*	*425*	***60***
Nose wiping procedure						
Recommended nose wipe	491	505	**97**	*39*	*407*	***10***

Four outcome categories

I devised four outcome categories from the events outlined in Tables 5.1 and 5.2 for further analysis to allow adjustment for the impact of clustering. I chose these categories because they represent the spectrum of the intervention measured by the observations; children's handwashing, staff handwashing and two routines. These categories are:

1. children's hands were washed as recommended after they used a toilet, had their nappy changed and before they ate food;
2. staff washed their hands as recommended after a nappy change;
3. staff used a disposable barrier on the change mat; and
4. staff wiped a child's nose by the recommended technique.

In each of the four categories, infection control practices during the trial were performed better in intervention centres than in control centres (Table 5.3).

Table 5.2b Nappy change procedure and nose wiping in intervention and control centres for six observation periods March to November 1996

	Observation 4						Observation 5						Observation 6					
	Autumn						Autumn						Autumn/ Winter					
	Intervention			*Control*			Intervention			*Control*			Intervention			*Control*		
	n	total	%	*n*	*total*	*%*	n	total	%	*n*	*total*	*%*	n	total	%	*n*	*total*	*%*
Nappy changes																		
Disposable barrier on mat	176	215	**82**	*65*	*222*	***29***	201	229	**88**	*74*	*227*	***33***	175	208	**84**	*86*	*232*	***37***
Gloves used	63	215	**29**	*91*	*222*	***41***	65	229	**28**	*63*	*227*	***28***	44	208	**21**	*58*	*226*	***26***
Remove gloves as recommended	35	63	**56**	*54*	*91*	***59***	38	65	**58**	*45*	*63*	***75***	29	44	**66**	*29*	*58*	***50***
Nose wiping procedure																		
Recommended nose wipe	88	92	**96**	*5*	*85*	***6***	90	90	**100**	*16*	*76*	***21***	65	66	**98**	*9*	*58*	***16***

Table 5.2c Nappy change procedure and nose wiping in intervention and control centres for six observation periods March to November 1996

	All Observations					
	Intervention			*Control*		
	n	total	%	*n*	*total*	*%*
Nappy changes						
Disposable barrier on mat	1054	1214	**87**	*380*	*1156*	***33***
Gloves used	338	1214	**28**	*425*	*1150*	***37***
Remove gloves as recommended	222	338	**66**	*255*	*425*	***60***
Nose wiping procedure						
Recommended nose wipe	491	505	**97**	*39*	*407*	***10***

Table 5.2a Nappy change procedure and nose wiping in intervention and control centres for six observation periods March to November 1996

	Observation 1						Observation 2						Observation 3					
	Autumn						Autumn						Autumn/ Winter					
	Intervention			*Control*			Intervention			*Control*			Intervention			*Control*		
	n	total	%	*n*	*total*	*%*	n	total	%	*n*	*total*	*%*	n	total	%	*n*	*total*	*%*
Nappy changes																		
Disposable barrier on mat	123	133	**92**	*55*	*137*	***40***	164	195	**84**	*47*	*180*	***26***	215	234	**92**	*53*	*158*	***34***
Gloves used	44	133	**33**	*61*	*137*	***45***	53	195	**27**	*92*	*180*	***51***	69	234	**29**	*60*	*158*	***38***
Remove gloves as recommended	26	44	**59**	*30*	*61*	***49***	41	53	**77**	*49*	*92*	***53***	53	69	**77**	*48*	*60*	***80***
Nose wiping procedure																		
Recommended nose wipe	78	79	**99**	*1*	*55*	***2***	87	94	**93**	*4*	*53*	***8***	83	84	**99**	*4*	*80*	***5***

Adjusted for clustering

Four outcome categories

Infection control practice for each of the four outcome categories ranged from 54 to 100 per cent in intervention centres and from one to 40 per cent in control centres (Table 5.3). However, adherence to 40 per cent in control centres was not representative of every centre in the control group. After adjusting for the effect of clustering and time, in a logistic regression model, performance of infection control practices was significantly better in intervention centres than in control centres in each of the four categories (Table 5.4).

Table 5.4 Adherence to recommended infection control practices in intervention centres compared with control centres, adjusted for clustering by centre and time

Infection control practice	Odds ratio	Robust* 95% CI	Robust* p value
Children's handwashing as recommended[†]	12	9,16	< 0.001
Staff handwashing as recommended[‡]	88	42,177	<0.001
Staff used a disposable barrier on the nappy change table	16	7,33	<0.001
Children's noses were wiped by staff members by the recommended technique[§]	550	237,1275	<0.001

*Standard error adjusted for clustering

[†]Handwash for a count of 20 before eating, after toileting and after nappy changes

[‡]Handwash for a count of 20 after changing a child's nappy

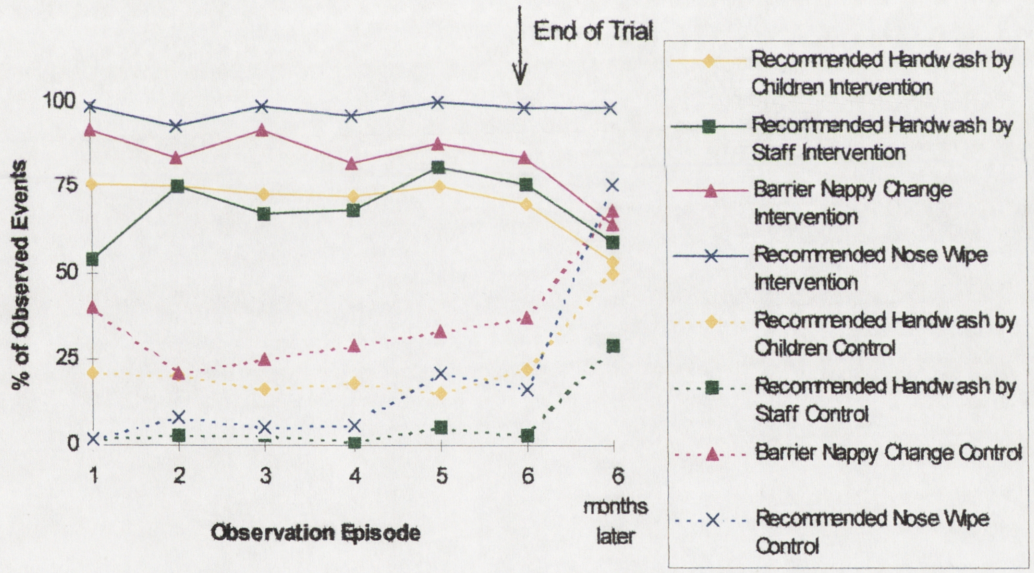
[§]A bag or glove barrier was used over hand or hands were washed for a count of 20 after the nose wipe

Performance six months after the trial

Comparison between intervention and control group

All four categories of practices improved in control centres six months after completion of the trial. Performance of two practices was still better in intervention centres compared with control: staff washing their own hands and the wiping of children's noses. However, the magnitude of difference between the intervention and control groups was lower than during the trial. Staff washing their own hands for the recommended duration was the item that improved the least in control centres (Figure 5.1).

Figure 5.1 Per cent compliance with four infection control categories, intervention and control centres for six observation episodes from March to November 1996 and one observation episode in June - July 1997



By logistic regression adjusting for clustering, recommended staff handwashing was three fold higher in intervention centres (Table 5.5). Although the odds ratio for performance of nose wiping was high (OR 25), both groups had high compliance with this item: approximately 100 per cent in intervention centres and 80 per cent in control control centres. There was no significant difference between intervention and control centres

six months later in two categories, children's handwashing and the use of disposable barriers (Table 5.5). The lack of a difference in these two categories was the result of a deterioration of performance in intervention centres combined with an improvement in control centres (Figure 5.1).

Table 5.5 Adherence to recommended infection control practices in intervention centres compared with control centres, adjusted for clustering by centre, six months after trial completion

Infection control practice	Odds ratio	Robust* 95 % CI	Robust* p value
Children's handwashing as recommended[†]	1.1	0.5,2.4	0.7
Staff handwashing as recommended[‡]	3.5	1.2,10	0.02
Staff used a disposable barrier on the nappy change table	0.85	0.2,4.5	0.9
Children's noses were wiped by staff members by the recommended technique[§]	25	2,29	< 0.01

* Standard error adjusted for clustering
[†] Handwash for a count of 20 before eating, after toileting and after nappy changes
[‡] Handwash for a count of 20 after changing a child's nappy
[§] A bag or glove barrier was used over hand or hands were washed for a count of 20

Comparison with own status group

Within the intervention group, performance of practices six months later deteriorated compared with their performance in the trial period for two categories. In control centres there was a significant improvement in performance in every category (Figure 5.1 and Table 5.6).

Table 5.6 Adherence to performance of infection control methods six months later compared to the group's own performance in the trial period adjusted for clustering by centre

Centre	Intervention			Control		
	Odds Ratio	**Robust* 95 % CI**	**Robust* pvalue**	**Odds Ratio**	**Robust* 95 % CI**	**Robust* p value**
Children's handwashing as recommended[†]	0.41	0.21,0.81	0.01	4.4	2.9,6.6	<0.0001
Staff handwashing as recommended[‡]	0.58	0.24,1.4	0.24	13	5.4,32	<0.0001
Staff used a disposable barrier on the nappy change table	0.28	0.85,0.91	0.03	4.9	1.3,19	0.02
Children's noses were wiped by staff members by the recommended technique[§]	2.4	0.35,16	0.37	31	5.3,181	<0.0001

* Standard error adjusted for clustering
[†] Handwash for a count of 20 before eating, after toileting and after nappy changes
[‡] Handwash for a count of 20 after changing a child's nappy
[§] A bag or glove barrier was used over hand or hands were washed for a count of 20

Performance in intervention centres by staff turnover

The staff turnover from the end of the trial to the six month observation was 24 per cent in the control group (44/186) and 22 percent in the intervention group (45/202). In the 10 intervention centres (one intervention centre had closed six months after the trial) the turnover of staff did impact on the continuation of practices (Table 5.7). In four centres where the staff turnover was high, handwashing had significantly deteriorated over the six months. When staff changes remained low, handwashing was not different six months later. For nose wiping and barrier use there was no deterioration in high staff turnover centres. Use of a barrier on the change mat was worse in centres with low staff changes.

Table 5.7 Adherence to performance of infection control methods six months later compared to the groups own performance for two groups of intervention centres (six centres with low staff turnover and four centres with high staff turnover) adjusted for clustering by centre

Centre	Staff turnover <= 20 per cent			Staff turnover > 37 per cent		
	Odds Ratio	Robust* 95 % CI	Robust* p value	Odds Ratio	Robust* 95 % CI	Robust* p value
Children's handwashing as recommended†	0.89	0.76,1.04	0.13	0.73	0.58,0.92	0.007
Staff handwashing as recommended‡	1.05	0.82,1.34	0.72	0.79	0.63,1.01	0.06
Staff used a disposable barrier on the nappy change table	0.65	0.48,0.88	0.006	0.90	0.60,1.34	0.62
Children's noses were wiped by staff members by the recommended technique§	1.32	1.06,1.62	0.01	1.07	0.77,1.49	0.68

* Standard error adjusted for clustering

† Handwash for a count of 20 before eating, after toileting and after nappy changes

‡ Handwash for a count of 20 after changing a child's nappy

§ A bag or glove barrier was used over hand or hands were washed for a count of 20

Tests for observer bias

I looked for evidence of bias by comparing the results in the first set of observations with the subsequent observations during the trial by logistic regression. The observer was blind to the status of the centres at the first observation. A significant difference was detected in only one out of eight comparisons (Table 5.8). Another method of detecting observer bias was in the recording of observations for the use of gloves in nappy changes. The use of gloves was not encouraged in the intervention training which emphasised good handwashing. The observer was not aware of this training item. Gloves were used significantly more for nappy changes in control centres than in intervention centres (37 per cent 425/1150 control, 28 per cent 338/1214 intervention, chi square p value = 0.003).

Table 5.8 Assessment of potential observer bias by comparison of observations in the 2nd to 6th trial observations compared with the 1st observation adjusted for clustering by centre

Infection control practice	Intervention Robust* p value	Control Robust* p value
Children's handwashing as recommended†	0.47	0.48
Staff handwashing as recommended‡	0.01	0.74
Staff used a disposable barrier on the nappy change table	0.35	0.19
Children's noses were wiped by staff members by the recommended technique§	0.49	0.06

* Standard error adjusted for clustering
† Handwash for a count of 20 before eating, after toileting and after nappy changes
‡ Handwash for a count of 20 after changing a child's nappy
§ A bag or glove barrier was used over hand or hands were washed for a count of 20

Discussion

Child care staff implemented infection control practices significantly better in intervention centres than in control centres during the entire trial period. After adjusting for clustering, the differences in the four outcome categories was at least a 12 fold higher performance in intervention centres (Table 5.4). With the exception of the use of sandwich bag barriers for nose wipes, these practices have been previously recommended to all child care staff in the guidelines *Staying Healthy in Child Care* [56], a copy of which was in every centre in the trial.

Clearly staff and children in all centres realised that performing a handwash is important. After toileting, a handwash of even short duration (any handwash) was carried out by 61 per cent of occurrences for children in control centres and after nappy changing by 90 per cent of occurrences for staff (Table 5.1c). The proportions in intervention centres were higher being 85 and 96 per cent respectively. However, the commitment to washing hands of even short duration (any handwash) in control centres dropped considerably in winter where after toileting only in 45 to 57 per cent of occurrences did children wash their hands at all (Table 5.1b).

The large difference between the two groups is whether a handwash was performed for the recommended count of 20. In control centres, this was managed in only 18 per cent of occurrences for children and three per cent of occurrences for staff (Table 5.3c). Respectively these were much higher in intervention centres being 73 per cent of occurrences for children and 71 per cent of occurrences for staff in intervention centres.

I believe that it was difficult for staff to understand the need for allocating time for washing hands: they did not appreciate that washing hands for a count of 10 and rinsing for a count of 10 was required to remove organisms. The practical demonstration of handwashing using *Glo Germ* helped change their attitude. By gaining the faith of the staff, both staff handwashing and children's

handwashing was performed as recommended. The staff helped the children by demonstrating handwashes and by developing songs about handwashing.

The practice that was implemented most easily was the new procedure of using sandwich bags over carer's hands as they held a tissue to wipe a nose. In the recordings, I asked the observer to accept either a nose wipe with a sandwich bag or a handwash for a count of 20 after the nose wipe as being a "recommended nose wipe". It is a pity that I combined these two options into one recording. Compliance with the recommended nose wipe was 97 per cent and the observer commented that rarely did she watch someone wash their hands after a nose wipe, almost every recommended nose wipe was with a sandwich bag barrier. The 10 per cent of attained recommended nose wipes in control centres were predominantly handwashes, occasionally staff used gloves. She did not observe any staff member using a sandwich bag in control centres.

One of the purposes of the observation in this trial was to determine if contamination of control groups occurred by spreading of methods from intervention centre staff to control centres. The nose wipe technique could have been the most readily transferred method as it was popular and easy to institute. This method was not adopted by any control centres during the trial. The difference between the two groups with all other methods also refutes the occurrence of contamination of the control group. I consider that many staff and directors in control centres were aware of the methods in the trial but because of their understanding of the role of a control group and their commitment to determining whether these practices reduced illness, they elected not to institute changes. An anecdotal example occurred when an intervention staff member attended an interview for a position in a control centre. During the interview she stated her knowledge of infection control practices gained from the intervention. The staff member was awarded the position but was informed by the director that they were a control centre and that the staff member was to perform her tasks as they stated, not using the new methods from the intervention centre.

The infection control practices were incorporated into child care centre routines but not without some obstacles. The economic cost of infection control practices was one. I addressed this by seeking inexpensive alternatives to traditional infection control aids. These included using computer paper as a paper barrier on nappy change tables, preparing liquid soap from soap flakes, and using plastic sandwich bags to protect hands when wiping a nose with a tissue. Another barrier was the quality of bathroom facilities. In some centres children could not access warm water to wash their hands and children would cry when their hands were put under cold water in winter. Access to any running water at all was a problem in the baby room in each centre. No baby room had a sink where those babies who could stand could wash their hands. Lifting these children to wash their hands under running water placed a physical strain on child care workers and we (myself and the staff) looked at alternative methods for washing babies hands. One approach we used involved high chairs attached to or near a sink to support the child's weight while the staff washed the child's hands. The director in one centre designed and used a metal frame to attach to the sink for the child to stand upon.

Compliance with the removal of gloves as soon as a child was clean was not well attained in intervention centres despite being a specific training item. After cleaning a child, leaving gloves on when the carer picks up the child's clothes or lifts the child back to the play room, allows contamination of the child and child care room with faecal organisms. In one instance the observer watched a carer return to the child's care room and perform other tasks before the glove was removed. It is likely that carers felt protected when they wore gloves and did not appreciate the risk this provided to the children through the environment.

There are some limitations to the observation phase of the trial. It would have been preferable to have had a measure of the practices before commencement of the trial, that is one observation before randomisation and training occurred. With this measure I could have determined the behaviour of intervention staff before and after training. This was not possible because of time constraints. I was notified in January 1996 that I was successful in obtaining funding. The trial

needed to commence by March to include the seasonal peaks of communicable disease and to have enough observation time of children before the end of the year. In January and February 1996 I recruited the 23 child care centres and children, designed the questionnaires, engaged the research company and participated in training the interviewers, conducted the pilot study to test the methods and recruited and trained the observer. I was unable to facilitate an observation in centres before the trial commenced.

Another limitation may have been bias by the observer. Her records of whether a handwash was performed as recommended was by counting slowly to 20. Because the studies about removal of organisms by handwashing use a duration of 15 to 20 seconds (Chapter 2 Literature Review), I considered it important to differentiate a thorough wash from a perfunctory wash. The observer may have counted more quickly in some centres than others. However I could not find a more objective way of measuring an adequate handwash. It would have been inappropriate for her to have been in the centres with a stop watch, this would have incurred the staff's curiosity and may have alerted them that handwashes were being timed. Two factors suggest that the observer was not biased:

- the lack of difference between observations two to six (when the observer may have deduced a centre's status) and the first observation (when the observer was blind to a centre's status) and
- a lack of higher glove use in intervention centres. The observer was not aware that I had not encouraged use of gloves in the training sessions and she expressed surprise that few of the intervention staff were using gloves.

The guidelines *Staying Healthy in Child Care,* are inadequate to encourage infection control practices without training. I believe that the success of this training was directly related to providing the training within the centres. On-site training allowed the staff to discuss the techniques and how they would work in their circumstances. One training session was sufficient to improve infection control practices as shown in the control centres. However, reinforcement of training needed to occur within six months by which time one quarter of staff in the centres in this trial were new. Even in intervention centres where the practices

were well instituted, there was deterioration of performance within six months. It is disappointing that the item that had improved the least in control centres six months after training was staff washing of their own hands for the recommended duration. This poor result may be the combination of new staff and lack of acceptance that recommended handwashes apply to adults as well as children.

Chapter 6 Results: Impact of the Intervention on Acute Diarrhoea

Overview

In this chapter I present the results of the impact of the intervention on diarrhoea in children. Parents reported whether their child had diarrhoea according to the definition provided on their daily symptom calendar. I calculated the incidence of diarrhoeal episodes for all children and for two age groups: 24 months of age or under, and over 24 months of age. I elected this age cut off because of child development and the results from the Kotch et al intervention study. Around 24 months of age is the time children start to toilet train and become independent with their toileting and handwashing. Kotch et al reported that their intervention only reduced diarrhoea in children under 24 months of age who had severe diarrhoea[3].

I developed a multivariable model to assess the impact of the intervention after adjusting for confounding and clustering by centre. Because there was a range in compliance with infection control procedures in intervention centres, I analysed the impact of the intervention after grading centres by performance from the observations outlined in Chapter 5. I approached the grading of centres by both "intent to treat" and "treatment received" analyses.

Impact of the intervention on symptom days

Definition of diarrhoea

I defined diarrhoea in terms of a parent report of two or more unusually loose or watery bowel motions in a 24 hour period. The number of days per child year of diarrhoea was lower in intervention centres than in control centres (Table 6.1).

Table 6.1 Days of diarrhoea symptom for 558 children in child care centres, March to November 1996, by intervention group

	No. of child days	No. of days of diarrhoea	Diarrhoea days per child year
Intervention	62,159	859	5.0
Control	51,518	964	6.8
All	113,677	1,823	5.9
Crude rate ratio			0.74 (0.68,0.82)

Impact of the intervention on episodes of diarrhoea

Definition of an episode

I defined a new episode of diarrhoea as the onset of diarrhoea following three consecutive symptom-free days.

Incidence

The incidence of episodes of diarrhoea was lower in children in intervention centres than in control centres (Table 6.2).

Table 6.2 Incidence of episodes of diarrhoea per child year by intervention status

Children	No. of diarrhoea episodes	No. of child days	Incidence per child year
Intervention	335	62,159	1.9
Control	380	51,518	2.7
All	715	113,677	2.3
Crude incidence rate ratio			0.73 (0.63,0.85)

Incidence by age group and sex

The crude rates by age group suggest that the intervention may have had an impact on older children (over 24 months of age) but not on younger children (Table 6.3).The incidence was slightly higher in female children, however the crude rate ratio shows no difference between the sexes of impact of the intervention (Table 6.4).

Table 6.3 Incidence of diarrhoea episodes by intervention status and age group

Age group	Status	No. of episodes	No. of child days	Incidence per child year	Incidence rate ratio (95 % CI)
<= 24 months	Intervention	208	22,620	3.4	
	Control	208	21,312	3.6	0.94 (0.77,1.15)
> 24 months	Intervention	127	39,539	1.2	
	Control	172	30,206	2.1	0.56 (0.44,0.71)
Total		715	113,677		

Table 6.4 Incidence of diarrhoea episodes by intervention status and sex

Sex	Status	No. of episodes	No. of child days	Incidence per child year	Incidence rate ratio (95 % CI)
Female	Intervention	184	31,211	2.2	
	Control	219	26,084	3.1	0.70 (0.57,0.89)
Male	Intervention	151	30,948	1.8	
	Control	161	25,434	2.3	0.77 (0.61,0.97)
Total		715	113,677		

Adjusted for season

Infectious diarrhoeal illness has a seasonal pattern with a peak in winter for rotavirus, the most common agent. I adjusted the risk of diarrhoeal episodes for the season by including a variable for each month in a Poisson regression model. After adjusting for season, the risk of diarrhoeal episodes was lower in intervention centres than in control centres. When stratified by age the risk was significantly lower in older children but not in younger children. This simple model adjusting for season and stratified by age is presented with two measures of standard error for confidence intervals and p values. The robust estimates allow for clustering by centre (Table 6.5).

Table 6.5 Relative risk of new episodes of diarrhoea in children in intervention centres after adjusting for season

Age	Relative risk	Robust 95 % CI	Robust p value	Standard 95 % CI	Standard p value
<=24 months	1.00	0.75,1.32	0.98	0.74,1.35	0.98
> 24 months	0.58	0.39,0.84	0.004	0.39,0.85	0.005
All	0.74	0.57,0.95	0.02	0.57,0.97	0.03

Development of multivariable model

The goal of the analysis was to obtain a single overall estimate of the effect of exposure to the intervention after adjusting for confounding factors. That is the goal was to obtain a valid estimate of the exposure disease relationship rather than obtaining a good predictive model of association. I used the modelling strategy proposed by Kleinbaum, where the stages are:

1. specification of variables,
2. interaction assessment, and
3. confounding assessment followed by precision[125].

Variable specification

I selected potentially confounding variables that could be expected biologically to affect susceptibility to gastrointestinal infections and variables that had been shown in the literature to be associated with acute diarrhoea. This provided the initial model (Tables 6.6 and 6.7).

Table 6.6 Child variables that potentially affect children's susceptibility to gastrointestinal infection

Potential confounder	Variable	Variable type
Age	Age in the middle of the trial	continuous
Sex	Sex	dichotomous
Weight at birth	Category of weight at birth	categorical
Breast feeding	1. Referent: Predominantly breast fed for six months or more 2. Ever breast fed 3. Never breast fed	categorical

Table 6.7 Environmental variables that potentially affect children's susceptibility to gastrointestinal infection

Potential confounder	Variables	
Child care history	First attended child care at age < six months	dichotomous
	New to child care in the last six months	dichotomous
	Attends any other child care in addition to the enrolled centre	dichotomous
Siblings	Sibling who lives in the child's home attends school	dichotomous
	Sibling who lives in the child's home attends child care	dichotomous
Crowding in the home	More that one child per bedroom	dichotomous
	Number of people who live in the home	continuous

I assessed interaction before considering confounding. I tested each variable nominated above with interaction with the exposure of the intervention using the Likelihood ratio test. Because the model aims to determine the exposure disease relationship, I did not pursue interactions between confounders alone. Three interaction terms were significant by this test: young age, sibling who attends child care and breast feeding, each interacted with the intervention status of the child's centre (Table 6.8).

Table 6.8 Impact of interaction terms by Likelihood ratio test on model with all variables

	Likelihood ratio test* p value
Young age * Status* (Age <=24 months)	0.0003
Sex * Status	0.38
Low birth weight * Status (Low birth weight, under 1500 grams)	0.41
Breast fed * Status, categorically graded as	0.02
1 breast fed predominantly for six months referent	
2 ever breast fed * Status	
3 never breast fed * Status	
Attends any other child care * Status	0.28
New to care * Status (First attending within the last six months)	0.33
First attended child care at < six months of age * Status	0.06
Sibling attends child care * Status	0.03
Sibling attends school * Status	0.28
Crowding * Status (More that one child per bedroom)	0.51
More than four persons live in the home * Status	0.09

*Status = intervention or control

Review of non-significant interaction terms in the multivariable model

I retested the 8 terms that were not significant when tested individually by a single test addition, adding to the model as a group. These interactions remained non-significant and were discarded from the model:

1. deviance of model with 8 interaction terms = 2576.23,
2. deviance of model with no interaction terms and 12 confounders = 2584.60,
3. deviance difference = 8.37, df 8 , p = 0.40.

Assessment of the significant interaction terms in the multivariable model

For the three interaction terms that were significant when tested individually, I explored by way of univariate analysis how these factors were impacting, either as causing effect modification alone or as a combination of effect modification and confounding.

Univariate analysis of significant interaction terms

Age

Exploration of the univariate analysis of the impact of age was presented in Table 6.5. The impact of the intervention was seen when children reach over 24 months of age.

Sibling attends child care

The intervention had a bigger impact on diarrhoea when there was not a sibling in care (Table 6.9). Having a sibling in care could increase the risk of disease as the sibling may acquire diarrhoea from care.

Table 6.9 Incidence rate ratio for episodes of diarrhoea by sibling in care

	Status	No. of episodes	No. of child days	Incidence	Incidence rate ratio
Sibling in care	Intervention	129	23,179	2.03	
	Control	122	20,831	2.13	0.95 (0.73,1.23)
No sibling in care	Intervention	206	38,980	1.92	
	Control	258	30,687	3.06	0.63 (0.52,0.75)
Total		715	113,677		

Breast feeding

The intervention had an impact when children had been breast fed. As breast feeding itself is a protective effect for diarrhoea it makes biological sense that breast feeding could potentiate the intervention's protective effect (Table 6.10). The impact of the intervention was greater when children had been predominantly breast fed for six months (Table 6.11).

Table 6.10 Incidence rate ratio for episodes of diarrhoea by ever breast fed

	Status	No. of episodes	No. of child days	Incidence	Incidence rate ratio
Never breast fed	Intervention	21	3,683	2.08	
	Control	12	2,593	1.69	1.23 (0.58,2.74)
Ever breast fed	Intervention	314	58,476	1.95	
	Control	368	48,925	2.75	0.71 (0.61,0.83)
Total		715	113,677		

Table 6.11 Incidence rate ratio for episodes of diarrhoea by predominantly breast fed for six months

	Status	No. of episodes	No. of child days	Incidence	Incidence rate ratio
Not predominantly breast fed for six months	Intervention	218	41,015	1.9	
	Control	220	33,677	2.4	0.81 (0.67,0.99)
Predominantly breast fed for six months	Intervention	117	21,144	2.0	
	Control	160	17,841	3.3	0.61 (0.48,0.79)
Total		715	113,677		

Effect modification

All four interaction terms appear to be having an effect modification impact without obvious confounding (Table 6.12).

Table 6.12 Interpretation of relative risks (RR) by strata for confounding or effect modification

Risk factor	Crude RR	Strata 1 RR	Strata 2 RR	Interpretation
Young age	0.73	0.93	0.56	Effect modification*
Ever breast fed	0.73	1.23	0.71	Effect modification*
Predominantly breast fed for six months	0.73	0.81	0.61	Effect modification*
Having a sibling in child care	0.73	0.95	0.63	Effect modification*

* Crude estimate of relative risk is between that of the strata estimates and the relative risk in each strata are substantially different

Backwards stepwise analysis of significant interaction terms

In stepwise assessment, all models with interaction terms were hierarchically formulated and included all potential confounders. By a group approach the three interaction terms were significant in comparison with a model with no interaction terms:

1. deviance of 3 interaction term (young * Status, sibling attends child care * Status and breast feeding score * Status) 12 confounder model = 2554.34,
2. deviance of no interaction terms 12 confounder model = 2584.60,
3. deviance difference 30.26, df = 4 p <.0001.

I tested the importance of each interaction term by backwards stepwise elimination.

Step 1

The least significant interaction term by the Wald test was breast feeding and status:

- young age * Status p = <.0001,
- sibling attends child care * Status p = 0.010,
- breast feeding score 2 ever fed * Status p=0.089, score 3 never fed * Status p=0.017.

After removing the breast feeding term, the Likelihood ratio test revealed this term was not significant:

1. deviance of 3 interaction 12 confounder model 2554.34,
2. deviance of 2 interaction 12 confounder model 2556.07,
3. deviance difference 1.73 , 2 df p= 0.42.

The term of breast feeding interaction with status was therefore removed from the model.

Step 2

The least significant interaction term in the two interaction (young * Status and sibling attends child care * Status) and 12 confounder model was sibling attends child care and status:

- young age * Status p = 0.001,
- sibling attends child care * Status p = 0.026.

Removing this significant term, the likelihood ratio test revealed this term was statistically significant:

1. deviance of 2 interaction 12 confounder model = 2556.07,
2. deviance of 1 interaction 12 confounder model = 2560.11,
3. deviance difference 4.04, 1 df p = 0.04.

Because the term remained statistically significant it was accepted in the model. Two interaction terms were therefore accepted for the final multivariable model:

- young age * Status and
- sibling attends child care * Status.

Final model

I considered confounding followed by precision. Kleinbaum states that the safest approach when interaction is present is to keep all potential confounders in the model[125]. I accepted that this would ensure control of confounding but may lack precision.

I accepted as the final multivariable model two interaction terms (young age * Status and sibling attends child care * Status), each month to adjust for seasonality and 11potential confounders listed in Tables 6.6 and 6.7. The model included whether a child was new to attending child care as discussed in Chapter 4.

Impact of the intervention fully adjusted

After adjusting for confounding and including two interaction terms, the intervention decreased episodes of diarrhoea by 50 per cent (Table 6.13).

Table 6.13 Relative risk of diarrhoea in intervention children fully adjusted for confounding

	Relative risk	Robust* 95 % CI	Robust* p value	Standard 95 % CI	Standard p value
All	0.50	0.36,0.68	<.0001	0.37,0.68	<.0001

* Standard Error adjusted for clustering by centre

Intracluster correlation coefficient

The intracluster correlation coefficient with diarrhoea episodes was 0.0052.

Fully adjusted model by age group

The fully adjusted model by age group includes only one interaction term (sibling attends care * Status) and 12 confounding variables. The second interaction term in the model across the full age range is age * Status. After stratification by age, this term is collinear with outcome status. Children were categorised as being <= 24 months (young = 1) and or older than 24 months (young = 0). When this term is multiplied by status (intervention = 1 and control = 0), the interaction term was the same as the intervention status term for all young children and was 0 for all control children. The fully adjusted model for age group stratification is therefore: one interaction term, 11 potential confounders from Tables 6.6 and 6.7, and the term month to adjust for seasonality.

Analysis by age group, fully adjusted for confounding shows that the impact of the intervention is only in the older age group. Diarrhoea episodes were reduced by 52 per cent in children over 24 months of age. Although the risk of diarrhoea

in young children appears also to have been reduced by 10 per cent, this is not a statistically significant result with wide confidence intervals around the point estimate.

Table 6.14 Relative risk of diarrhoea episodes after adjusting for effect modification and confounding, by age group

Age group	Relative risk	Robust* 95 % CI	Robust* p value	Standard 95 % CI	Standard p value
<=24 months	0.90	0.67,1.19	0.44	0.65,1.24	0.51
> 24 months	0.48	0.29,0.78	0.003	0.33,0.68	0.0001

* Standard Error adjusted for clustering by centre

Compliance with infection control practices

I graded performance of infection control practices in intervention and control centres using the observation data (Chapter 5). For this analysis I selected the observations of children washing their hands as recommended after nappy changes, after toileting and before eating. Each centre has its own compliance score for each observation. The range of compliance is different from those discussed in Chapter 5, where compliance is reported as an aggregate for each observation episode in each intervention group. In intervention centres the compliance with children's handwashing in over six observations ranged from 53 to 95 per cent, while in control centres the range was from 0 to 34 per cent.

Compliance "intent to treat"

I graded intervention centres compliance into three groups. That is for child handwashing practice the intervention centre has a score of low, moderate or high compliance. In this analysis, control centres represented the referent population. When children's compliance with handwashing was very high (over 81 per cent) diarrhoea was reduced by 57 per cent (Table 6.15).

Table 6.15 Relative risk (RR) of episodes of diarrhoea (relative to control centres) after adjusting for confounding, graded by the intervention centre children's compliance with handwashing

Handwash group*	RR	Robust† 95 % CI	Robust† p value	Standard 95% CI	Standard p value
Control	1.00				
1	0.52	0.38,0.72	<.0001	0.37,.0.75	<.0001
2	0.53	0.37,0.76	<.0001	0.37,0.75	<.0001
3	0.43	0.27,0.70	<.0001	0.29,0.64	<.0001

* Handwash group 1 = lowest compliance rate (53-69%) for 4 centres
Handwash group 2 = moderate compliance rate (70-79%) for 4 centre
Handwash group 3 = high compliance rate (over 80%) for 3 centres
† Standard Error adjusted for clustering by centre

Compliance, "intent to treat" by age group

The reduction of acute diarrhoea in older children was greatest with high compliance. Among this age group, high compliance with infection control practices in intervention centres reduced diarrhoea by 66 per cent in comparison with control centres. However, even with high compliance, the intervention did not significantly reduce diarrhoea in young children (Table 6.16).

Table 6.16 Relative risk (RR) of episodes of diarrhoea (relative to control centres) after adjusting for confounding* and clustering by centre for three groups of children's handwashing compliance among intervention centres, by age group

Age group	Children's handwashing group†	RR	Robust‡ 95 % CI	Robust‡ p value
<= 24 months	Control	1		
	1	0.98	0.63,1.54	0.94
	2	0.85	0.58,1.24	0.39
	3	0.87	0.57,1.33	0.53
> 24 months	Control	1		
	1	0.43	0.29,0.63	<.0001
	2	0.62	0.36,1.09	0.10
	3	0.34	0.17,0.65	0.001

* The multivariable model when stratified by age includes 1 interaction term and 12 confounders
† Handwash group 1 = lowest compliance rate (53-69%) for 4 centres
Handwash group 2 = moderate compliance rate (70-79%) for 4 centre
Handwash group 3 = high compliance rate (over 80%) for 3 centres
‡ Standard Error adjusted for clustering by centre

Compliance "treatment received"

I graded all centres irrespective of their randomisation in an approach of "treatment received". In this analysis the referent group was 8 centres with poor compliance for child handwashing. When considering infection control practices in all centres this way, there is a dose response effect where improvement in performance of practices leads to a reduced risk of diarrhoea. High compliance with individual practices of handwashing was associated with reduction of diarrhoea episodes by 45 per cent (Table 6.17).

Table 6.17 Relative risk (RR) of episode of diarrhoea (relative to lowest compliant centres) after adjusting for confounding for three groups of children's handwashing compliance

Handwash group*	RR	Robust† 95% CI	Robust† p value	Standard 95% CI	Standard p value
1	1.00				
2	0.75	0.52,1.06	0.11	0.56,1.00	0.049
3	0.55	0.37,0.82	0.004	0.39,0.78	0.001

* Children's handwash group 1= referent lowest compliance (< 25 %) for 8 centres
Children's handwash group 2 = moderate compliance (25-69 %) for 8 centres
Children's handwash group 3 = high compliance (> 70%) for 7 centres
† Standard Error adjusted for clustering by centre

Compliance, "treatment received" by age group

Grading of infection control practices in all centres irrespective of randomisation by each age group shows the risk of diarrhoea to decrease in a dose response as compliance increased. However, in younger children the decrease in diarrhoea did not attain statistical significance. In children over 24 months of age the decrease is of borderline significance (Table 6.18).

Table 6.18 Relative risk (RR) of episode of diarrhoea (relative to lowest compliance) after adjusting for confounding variables and clustering by centre for three groups of children's handwashing compliance, by age group

Age group	Handwash group*	RR	Robust† 95 % CI	Robust† p value
<= 24 months	1	1.00		
	2	0.89	0.63,1.24	0.48
	3	0.80	0.38,1.12	0.19
> 24 months	1	1.00		
	2	0.76	0.40,1.40	0.55
	3	0.55	0.28,1.07	0.08

* Handwash group 1= referent lowest compliance (< 25%) for 8 centres
Handwash group 2 = moderate compliance (25 - 69%) for 8 centres
Handwash group 3 = high compliance (> 70%) for 7 centres
† Standard Error adjusted for clustering by centre

Child absence from child care with diarrhoea

The rate of absenteeism with diarrhoea was slightly lower in intervention centres than in control centres (Table 6.19).

Table 6.19 Number of days of child absence from child care with diarrhoea

Intervention status	Number of absent days	Number of child days	Days per child year
Intervention	210	62,159	1.2
Control	203	51,518	1.4
Total	413	113,677	1.3

Table 6.20 Relative risk (RR) of days absent from child care after adjusting for confounding

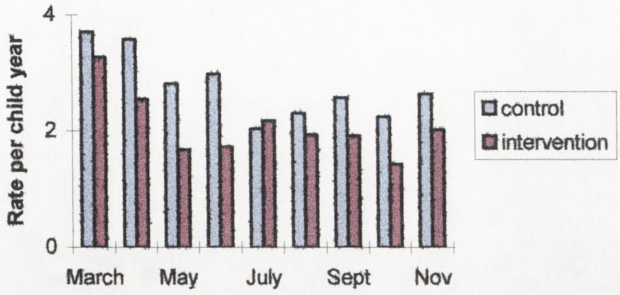
	RR	Robust* 95 % CI	Robust* p value	Standard 95 % CI	Standard p value
Absent from care with diarrhoea	0.54	0.28,1.05	0.07	0.36,0.82	0.004

* Standard Error adjusted for clustering by centre

Rate by month and comparison with surveillance of rotavirus

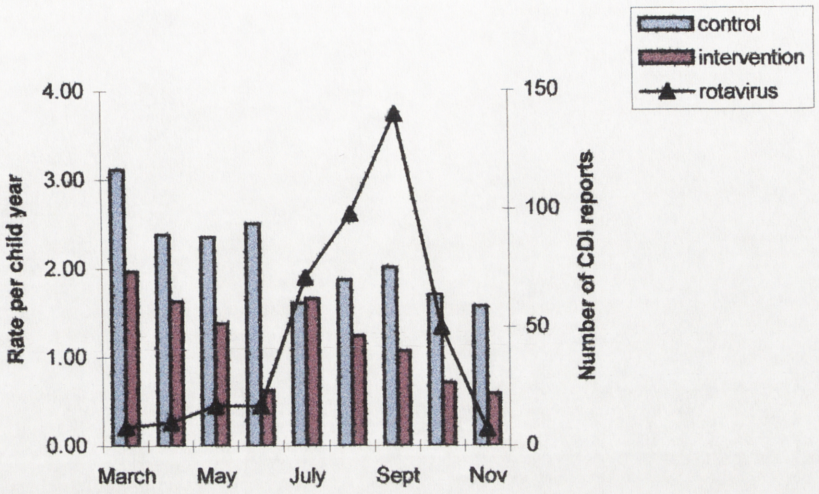
The rate of episodes of diarrhoea in intervention and control centres in each month of 1996 is presented in Figure 6.1. The highest rate of illness in both groups of centres was in March. However, this is likely to be misleading as in this month there were fewer days of surveillance of child illness compared with other months of the trial: there were approximately 4,000 days of child surveillance for March compared with 14,000 for each month from April to October and 9,000 in November. There was no apparent seasonal pattern of diarrhoeal illness during the months of surveillance.

Figure 6.1 Rate of diarrhoea per child year by month



The significant reduction in diarrhoea from the intervention was in children over 24 months of age. The lower rate of diarrhoea in these children in intervention centres was present in every month except July (Figure 6.2). The intervention may have impacted on the most common cause of diarrhoea in children in care, rotavirus, or it may have interrupted transmission of more than one pathogen. One possible reason for reduction in diarrhoea in older but not younger children is that the intervention may have impacted on different organisms. To appraise whether the intervention impacted on rotavirus I obtained data about this virus presence in 1996 from the Communicable Diseases Intelligence LabVISE scheme. This is a passive surveillance system of reports of virus detection in stool specimens sent to clinical laboratories around Australia. I selected reports from the ACT and surrounding state New South Wales (NSW) laboratories, NSW reports were included because there were few reports from the ACT and the two areas a geographically adjacent. Reduction in diarrhoea in August and September coincided with high numbers of reports of rotavirus. However it is clear that reduction in diarrhoeal episodes was also present in other months of the year when rotavirus was not prevalent.

Figure 6.2 Rate of diarrhoea per child year by month in children over 24 months of age and surveillance reports of rotavirus from NSW and ACT laboratories (CDI LabVISE scheme), March to November 1996



Discussion

The infection control intervention reduced diarrhoea in children. However, the impact of this intervention was confined to older children (over 24 months of age) in whom diarrhoea was reduced by 52 per cent (Table 6.14, RR 0.48, 95 % CI 0.29-0.78 p = 0.003). In younger children there was a lower risk of illness of 10 per cent however, this was not a statistically significant result. High compliance with children's handwashing was associated with the lowest risk of diarrhoea. By "intent to treat" analysis, high compliance with handwashing in the older age group of children related to a reduction in diarrhoeal episodes of 66 per cent (Table 6.16, RR 0.34 , 95% CI 0.17-0.65 p = 0.001).

These results initially appear to contradict those from by Kotch et al who reported an impact only in younger children (under 24 months of age). Kotch et al found only "severe" diarrhoea episodes were reduced in this age group, they did not find a change in "all" episodes of diarrhoea [3]. Although I found no reduction in diarrhoea in the younger age group, I did not separately identify

"severe" from "all" episodes of diarrhoea. I therefore could not identify if there was a reduction in "severe" episodes.

In older children in control centres, the rate of 2.1 episodes per child year was similar to that of "all diarrhea"reported by Kotch et al of 2.8 per child year. Where Kotch et al found no reduction in children over 24 months of age, I found significant and substantial reduction. Unlike their work, this intervention did impact on children's behaviour, and presumably on child to child transmission as shown by observations of children's handwashing. Children's behaviour and potential exposure to organisms may be a reason why the intervention only reduced diarrhoeal illness in older children. Children over 24 months of age are either independent with their toileting or are in the process of learning that independence. This may result in less consistent handwashing and hygiene at toileting. Children in this age group are allowed to be alone in the bathroom, both to encourage their independence and because the group sizes are too large for carer s to observe every child in the bathroom. As the observer recorded, the handwashing became an accepted routine for older children who managed their own hands. This acceptance of the routine by older children could have impacted on child to child transmission, leading to reduction in illness in this older age group. Although handwashing has been long recognised as a capable intervention, its effectiveness has been limited in other settings such as hospitals by such acceptance and compliance[120]. Children's propensity to cling to routine, together with the use of a routine that was relevant to child behaviour (the use of songs about handwashing) aided compliance in child care.

There is another other plausible reason for why there was a different impact on older compared with younger children. Different pathogens are prevalent between age groups and these may be differentially affected by hand and fomite contamination. Bartlett found *Giardia* to be more common in older children and rotavirus more common in younger children[8]. Transmission of *Giardia,* which is more hardy and able to survive on environmental surfaces for longer periods than rotavirus, could therefore be more susceptible to an infection control intervention. It would have been an advantage if I had been able to measure the

pathogens in unwell children throughout the trial, but this was beyond my resources.

Application of this intervention to all child care centres in Australia could have a large impact on disease. In 1996, 88,200 Australian children between 24 months and 59 months of age, the age of children in the older age group of this cohort, attended long day care centres[130]. With an incidence of 2.1 episodes per child year, these children suffer from 185,220 episodes of acute diarrhoea. With this intervention and high compliance within child care centres 66 per cent of these infections could be prevented representing a total of 122,245 infections per year.

Chapter 7 Results: Impact of the Intervention on Acute Respiratory Infection

Overview

This chapter presents the results of the impact of the intervention on respiratory infections in children. Parents reported about the presence of three respiratory symptoms in their child for every day and these were used in an algorithm to define an episode of cold. Once defined, I calculated the incidence of cold for all children and in two age groups: less than or equal to 24 months, and over 24 months. I elected these age groups because of the evidence from the Wald longitudinal study according to which children in care in the first two years of their lives had a higher incidence of respiratory infection than children at home, while in their third year of life there was no difference between the two groups. A multivariable model was used to assess the impact of the intervention after adjusting for confounding and clustering by centre.

As with the diarrhoea analysis in Chapter Six, I analysed the impact of the intervention after grading centres by performance of infection control practice. I approached this by both "intention to treat" and "treatment received analyses", using the multivariable model adjusting for confounding and clustering.

This chapter also includes results of the impact of the intervention with a modified case definition. The case definition for the results presented above did not allow cough as a sole symptom of an acute respiratory illness. This was because asthma or acute reactive airways disease rather than a cold was likely to exhibit cough alone. The modified case definition allowed the occurrence of cough as a sole symptom to meet the criteria of a cold. Although I do not accept that this should be a case definition for an episode of cold, the pattern of impact with high compliance was similar to that seen with the original definition.

Impact of the intervention on symptom days

The number of days children had respiratory symptoms ranged from 21 days per child year to 91 days per child year. There were fewer days of runny nose and blocked nose symptoms in children in the intervention group than in children in the control group. However, more days of cough were reported in children in the intervention group (Table 7.1).

Table 7.1 Days of respiratory symptoms for 558 children in child care centres, March to November 1996, by intervention group

	No. of child days	No. of runny nose days	Runny nose days per child year	No. of blocked nose days	Blocked nose days per child year	No. of cough days	Cough days per child year
Intervention	62,159	14,882	87	3,306	19	12,431	73
Control	51,518	12,774	91	3,256	23	9,573	68
All	113,677	27,656	89	6,562	21	22,004	71

Impact of the intervention on episodes of cold

Definition of an episode of a cold

To assess the impact of the intervention on episodes of acute infections, I used a definition of a cold that was modified from a community intervention trial of virucidal impregnated tissues[105]. An episode of a cold was defined as a parent report of:

- any two of the symptoms of runny nose, blocked nose or cough on any one day, or
- any two of the symptoms of runny nose, blocked nose or cough for two consecutive days but not including two consecutive days of cough alone.

I classed the occurrence of a cold as a new episode of cold if it followed three symptom free days. I did not accept two consecutive days of cough with no other respiratory symptom as meeting a definition acute respiratory infection because cough alone was more likely to represent asthma or reactive airways disease. This definition was similar to that used by Wald et al in a longitudinal child care study[65]. They defined a simple upper respiratory infection as a runny nose or blocked nose with or without a cough for one day or more and considered an illness episode as a new episode when symptoms occurred after three days of normal activity with no respiratory symptoms.

Incidence

The incidence of cold was lower in intervention centres than in control centres (Table 7.2).

Table 7.2 Incidence of episodes of cold per child year by intervention status

Children	No. of colds	No. of child days	Incidence per child year
Intervention	1,716	62,159	10.1
Control	1,547	51,518	11.0
All	3,263	113,677	10.5
Crude incidence rate ratio			0.92 (0.86,0.99)

Incidence by age group and sex

The crude rates suggest that the intervention may have had an impact on children 24 months of age or younger but not on children over 24 months of age (Table 7.3).The incidence of colds was slightly higher in male children, however, the crude rate ratio suggests impact of the intervention was slightly greater in females (Table 7.4).

Table 7.3 Incidence of colds by intervention status and age group

	Status	No. of colds	No. of child days	Incidence per child year	Incidence rate ratio (95 % CI)
<= 24 months	Intervention	707	22,620	11.4	
	Control	761	21,312	13.0	0.88 (0.79,0.97)
> 24 months	Intervention	1,009	39,539	9.3	
	Control	786	30,206	9.5	0.98 (0.89,1.07)
Total		3,263	113,677		

Table 7.4 Incidence of colds by intervention status and sex

	Status	No. of colds	No. of child days	Incidence per child year	Incidence rate ratio (95 % CI)
Female	Intervention	843	31,211	9.9	
	Control	776	26,084	10.9	0.91 (0.82,1.00)
Male	Intervention	873	30,948	10.3	
	Control	771	25,434	11.1	0.93 (0.84,1.03)
Total		3,263	113,677		

Adjusted for season

Viral upper respiratory infections have a seasonal pattern with peak episodes in winter and spring. I adjusted the risk of colds for the season by including a variable for each month in a Poisson regression model. Across the full age range, the risk of colds after adjusting for the season was lower in intervention centres than in control. However, this was of borderline statistical significance. The reduction in illness appeared in children 24 months of age or under. This simple model adjusted for seasonality is presented with two measures of standard error for confidence intervals and p values. The robust estimates allow for clustering by centre (Table 7.5).

Table 7.5 Relative risk of new episodes of cold in children in intervention centres compared with control centres after adjusting for season

Age	Relative risk	Robust* 95 % CI	Robust* p value	Standard 95 % CI	Standard p value
<=24 months	0.88	0.82,0.96	0.003	0.80,0.98	0.02
> 24 months	0.98	0.88,1.09	0.69	0.85,1.12	0.76
All	0.93	0.86,1.00	0.06	0.82,1.05	0.23

* Standard Error adjusted for clustering by centre

Development of multivariable model

The goal of the analysis was the same as that in Chapter 6, to obtain a single overall estimate of the effect of exposure to the intervention after adjusting for confounding factors. I used the modelling strategy proposed by Kleinbaum where the stages are:

1. specification of variables
2. interaction assessment, and
3. confounding assessment followed by precision[125].

Variable specification

I selected potentially confounding variables that could be expected biologically to be associated with respiratory diseases and variables that had been shown in the literature to be associated with acute respiratory illness. This provided the initial model (Tables 7.6 to 7.7).

Table 7.6 Child variables that potentially confound the child's susceptibility to respiratory infection

Potential confounder	Variables	Variable type
Age	Age in the middle of the trial	Continuous
Sex	Sex	Dichotomous
Weight at birth	Category of weight at birth	Categorical
Asthma	Frequency of wheeze reported by parents in the 12 months prior to the trial	Categorical
	Whether a doctor ever stated this child has asthma	Dichotomous
Smoking during the child's pregnancy	Smoking during the child's pregnancy	Dichotomous
Breast feeding	If the child was predominantly breast fed for six months or more	Dichotomous

Table 7.7 Environmental variables that potentially confound the child's susceptibility to respiratory infection

Potential confounder	Variables	Variable type
Child care history	First attendance at less than six months of age	Dichotomous
	First attended child care within the last six months	Dichotomous
Siblings	Sibling who lives in the child's home attends school	Dichotomous
	Sibling who lives in the child's home attends child care	Dichotomous
Crowding in the home	More that one child per bedroom	Dichotomous
Exposure to smoking	Smoking in the home	Dichotomous
	Any adult who lives in the home smokes, whether smokes inside or not	Dichotomous
Heating at home	Gas	Dichotomous
	Wood fire	Dichotomous

Following the strategy, I tested for interaction before confounding. Because the model aims to determine the exposure disease relationship, I tested for the presence of effect modification using the variables listed above as interaction terms with the intervention status of the child's centre. I did not include interactions between confounders alone as would be pursued in a predictive multivariable model. I assessed importance of the interaction terms by the Likelihood ratio test, being the deviance difference between interaction term model with confounders and confounders only model. No interaction term was of significance in the respiratory illness model (Table 7.8).

Table 7.8 Impact of interaction terms by Likelihood ratio test on model with all variables

Interaction term	p value Likelihood ratio test
Young age * Status (Age <=24 months)	0.20
Sex * Status	0.82
Low birth weight * Status (Low birth weight = under 1500 grams)	0.13
Preterm birth * Status (More than two weeks preterm)	0.47
Smoking during the child's pregnancy* Status	0.65
Breast fed * Status (If the child was predominantly breast fed for six months or more)	0.53
Asthma * Status (Whether a doctor ever stated the child has asthma)	0.30
New to child care * Status (First attending care within the last six months)	0.78
Sibling attends child care * Status	0.86
Sibling attends school * Status	0.33
Crowding * Status (More that one child per bedroom)	0.30
Exposure to smokers at home * Status	0.92
Definite smoking inside the home * Status	0.66
Wood heating * Status	0.41
Gas heating * Status	0.45

I next assessed for confounding followed by consideration of precision. I aimed to obtain a valid point estimate of the exposure disease relationship that controls for confounding. First I assessed the removal of each potential confounder from the model of all variables (Table 7.9). I assessed the importance of removal of variables by whether the relative risk was the same as the relative risk of the gold standard model that included all potential confounders. If the relative risk of the new model equalled the gold standard, the variable could be dropped from the model if this resulted in improved precision. The model improved precision if there was a narrowing of the range of the confidence interval.

After assessing variables individually, I then assessed the impact of subsets or groups of potential confounders (Table 7.10). I considered the impact on the relative risk and precision as noted above.

There was no meaningful impact on the relative risk and no improvement in precision by removal of any single variable from the full model (Table 7.9). Similarly, no subset of variables identified the same relative risk as the full model whilst improving precision (7.10). I therefore rejected any model in which variables had been removed and accepted as the final fully adjusted model all 16 potentially confounding variables along with a variable for each month to allow for seasonality (Tables 7.6 and 7.7). The model included whether a child was new to attending child care as discussed in Chapter 4.

Table 7.9 Impact of removal of each single variable from the full model on the relative risk (RR) of episodes of cold

Model	RR	Robust* 95% CI	Interpretation†
Full 17 variable model	0.95	0.89,1.01	
Gold Standard			
Remove young age (<=24 months)	0.94	0.89,1.00	Not removed (a)
Remove sex	0.95	0.89,1.01	Not removed (b)
Remove young attendance	0.95	0.89,1.01	Not removed (b)
Remove sibling in child care	0.95	0.89,1.01	Not removed (b)
Remove sibling in school	0.95	0.89,1.01	Not removed (b)
Remove crowding	0.95	0.89,1.01	Not removed (b)
Remove smoking in pregnancy	0.95	0.89,1.01	Not removed (b)
Remove gas heating	0.95	0.88,1.01	Not removed (b)
Remove wood heating	0.95	0.88,1.01	Not removed (b)
Remove predominantly breast fed for six months	0.95	0.89,1.01	Not removed (b)
Remove wheeze in last 12 months	0.95	0.89,1.01	Not removed (b)
Remove asthma diagnosis	0.95	0.89,1.01	Not removed (b)
Remove weight at birth	0.95	0.89,1.01	Not removed (b)
Remove new to child care	0.94	0.88,1.01	Not removed (a)
Remove smoking inside the home	0.95	0.89,1.01	Not removed (b)
Remove an adult who lives in the home smokes	0.95	0.89,1.01	Not removed (b)

* Standard Error adjusted for clustering by centre

† (a)Does not equal RR of gold standard and does not control for confounding
(b)RR equals gold standard and controls for confounding but there is no gain in precision

Table 7.10 Multivariable model with subsets of confounders, ability to adjust for confounding by comparison with relative risk (RR) of gold standard, and ability to improve precision by narrowing of confidence intervals

Model	RR	Robust * 95 % CI	Interpretation†
Full 17 variable model Gold Standard	0.95	0.89,1.01	
2 variable model Season, young age <=24 months	0.94	0.87,1.01	Not accepted (a)
3 variable model Season, young age, parent smokes	0.94	0.87,1.01	Not accepted (a)
3 variable model Season, age, parent smokes	0.94	0.88,1.00	Not accepted (a)
3 variable model Season, sibling in school, sibling in child care	0.93	0.86,1.00	Not accepted (a)
4 variable model Season, new to child care, crowding in the home, smoking inside the home	0.94	0.88,1.01	Not accepted (a)
5 variable model Season, sex, sibling in child care, wood heating, predominantly breast fed for six months	0.93	0.86,1.00	Not accepted (a)
5 variable model Season, age, weight at birth, wheeze reported by parent, parent smokes	0.94	0.88,1.01	Not accepted (a)
5 variable model Season, predominantly breast fed for six months, wheeze reported by parent, asthma diagnosis, weight at birth	0.93	0.86,1.00	Not accepted (a)
6 variable model Season, sibling in school, young when first attended child care, wood heating, gas heating, wheeze reported by parent	0.93	0.86,1.00	Not accepted (a)
7 variable model Season, young age <=24 months, predominantly breast fed for six months, wheeze reported by parent, asthma diagnosis, weight at birth, parent smokes	0.94	0.87,1.01	Not accepted (a)
8 variable model Season, sibling in school, sibling in child care, crowding at home, smoking inside the home, parent smokes, wood fire heating, gas heating	0.93	0.86,1.00	Not accepted (a)
11 variable model Season, sibling in school, sex, young when first attended child care, sibling in child care, crowding in the home., wood fire, predominantly breast fed for six months, parent report of wheeze, asthma diagnosis, parent smokes	0.93	0.87,0.99	Not accepted (a)

* Standard Error adjusted for clustering by centre

† (a) RR does not equal gold standard and does not control for confounding

(b) RR equals gold standard and controls for confounding but there is no gain in precision

Impact of the intervention fully adjusted and by age group

After adjusting for confounding, there was no significant reduction in colds in children in intervention centres across the full age range. However, a significant reduction in colds was present in children 24 months of age or under (Table 7.11).

Table 7.11 Relative risk of cold in intervention children after adjusting for confounding, by age group

Age group	Relative risk	Robust* 95 % CI	Robust* p value	Standard 95 % CI	Standard p value
<=24 months	0.90	0.83,0.97	0.01	0.81,1.00	0.05
> 24 months	0.98	0.90,1.08	0.78	0.89,1.10	0.88
All	0.95	0.89,1.01	0.10	0.98,1.03	0.22

* Standard Error adjusted for clustering by centre

Intracluster correlation coefficient

The intracluster correlation coefficient with episodes of colds was 0.0026.

Compliance, "intent to treat"

Using the observation data, I scored each intervention centre for compliance with nose wiping technique and children's handwashing. The compliance by centre for children washing their hands are graded into three tiers, that is, each intervention centre has a score of low, intermediate or high compliance. For compliance with nose wiping, the segregation could only be divided into two scores as overall compliance was very good (range 87 to 100 per cent).

As compliance improved, the risk of colds decreased. There is a dose response effect where high compliance for both children's handwashing and staff nose wiping technique increased the reduction of colds (Table 7.12 and 7.13).

Table 7.12 Relative risk (RR) of cold (relative to control centres) after adjusting for confounding, graded by the intervention centre children's compliance with handwashing

Handwash group*	RR	Robust† 95 % CI	Robust† p value	Standard 95% CI	Standard p value
Control	1.00				
1	1.03	0.95,1.12	0.52	0.93,1.13	0.60
2	0.93	0.86,1.00	0.07	0.84,1.02	0.14
3	0.89	0.82,0.97	0.01	0.81,0.99	0.03

* Handwash group 1 = lowest compliance rate (53-69%) for 4 centres
Handwash group 2 = moderate compliance rate (70-79%) for 4 centres
Handwash group 3 = high compliance rate (over 80%) for 3 centres
† Standard Error adjusted for clustering by centre

Table 7.13 Relative risk (RR) of cold (relative to control centres) after adjusting for confounding, graded by the intervention centre staff's compliance with nose wipe method

Nose wipe group *	RR	Robust† 95 % CI	Robust† p value	Standard 95% CI	Standard p value
Control	1.00				
1	1.00	0.92,1.08	0.98	0.89,1.12	0.98
2	0.93	0.86,0.99	0.04	0.85,1.01	0.08

* Nose wipe group 1 = moderate compliance rate (87-96%) for 4 centres
Nose wipe group 2 = high compliance rate (97-100%) for 7 centres
† Standard Error adjusted for clustering by centre

Compliance, "intent to treat" by age group

The dose response effect and impact of the intervention is seen in younger children but not in those over 24 months of age (Table 7.14 and 7.15).

Table 7.14 Relative risk (RR) of cold (relative to control centres) after adjusting for confounding and clustering by centre for three groups of children's handwashing compliance among intervention centres, by age group

Age group	Handwash group *	RR	Robust † 95 % CI	Robust † p value
<= 24 months	Control	1		
	1	0.98	0.84,1.14	0.80
	2	0.91	0.85,0.98	0.01
	3	0.83	0.76,0.90	<.001
> 24 months	Control	1		
	1	1.04	0.95,1.14	0.35
	2	0.95	0.82,1.10	0.47
	3	0.97	0.86,1.09	0.59

* Handwash group 1 = lowest compliance rate (53-69%) for 4 centres
Handwash group 2 = moderate compliance rate (70-79%) for 4 centres
Handwash group 3 = high compliance rate (over 80%) for 3 centres
† Standard Error adjusted for clustering by centre

Table 7.15 Relative risk (RR) of cold (relative to control centres) after adjusting for confounding and clustering by centre for two groups of nose wiping compliance among intervention centers, by age group

Age group	Nose wipe group *	RR	Robust† 95 % CI	Robust† p value
<= 24 months	Control	1		
	1	0.92	0.82,1.02	0.12
	2	0.89	0.82,0.98	0.01
> 24 months	Control	1		
	1	1.03	0.89,1.20	0.67
	2	0.97	0.86,1.09	0.57

* Nose wipe group 1 = moderate compliance rate (87-96%) for 4 centres
Nose wipe group 2 = high compliance rate (97-100%) for 7 centres
† Standard Error adjusted for clustering by centre

Compliance, "treatment received"

I graded all centres' performance irrespective of randomisation to analyse in an approach of "treatment received". In this analysis the referent group was eight centres with poor compliance. Every centre was graded for compliance with nose wiping and children washing their hands. The performance of children washing their hands or staff wiping the children's noses are each graded into three tiers, that is each centre has a score of low, moderate or high. There is a dose response where improved compliance for both children's handwashing and staff's nose wiping increased the reduction of colds (Table 7.16 and 7.17) .

Table 7.16 Relative risk (RR) of cold (relative to lowest compliance centres) after adjusting for confounding for three groups of children's handwashing compliance

Handwash group*	RR	Robust† 95% CI	Robust† p value	Standard 95% CI	Standard p value
1	1.00				
2	1.02	0.97,1.08	0.43	0.94,1.12	0.62
3	0.92	0.86,0.97	0.004	0.83,1.00	0.06

*Handwash group 1 = referent lowest compliance (< 25%) for 8 centres
Handwash group 2 = moderate compliance (25- 69%) for 8 centres
Handwash group 3 = high compliance (>70%) for 7 centres
† Standard Error adjusted for clustering by centre

Table 7.17 Relative risk (RR) of colds (relative to lowest compliance centres) after adjusting for confounding variables and clustering by centre for three groups of nose wiping compliance

Nose wipe group*	RR	Robust† 95% CI	Robust† p value	Standard 95% CI	Standard p value
1	1.00				
2	0.99	0.93,1.04	0.60	0.89,1.09	0.76
3	0.92	0.85,0.99	0.03	0.84,1.01	0.08

*Nose wipe group 1 = referent lowest compliance (< 10%) for 8 centres
Nose wipe group 2 = moderate compliance (10 - 96%) for 8 centres
Nose wipe group 3 = high compliance (97-100%) for 8 centres
† Standard Error adjusted for clustering by centre

Compliance, "treatment received" by age group

The dose response effect, irrespective of randomisation, is present with children 24 months of age or under but not with children over 24 months of age (Table 7.18 and 7.19).

Table 7.18 Relative risk (RR) of cold (relative to lowest compliance) after adjusting for confounding variables and clustering by centre for three groups of children's handwashing compliance, by age group

Age Group	Handwash Group*	RR	Robust† 95 % CI	Robust† p value
<= 24 months	1	1.00		
	2	0.96	0.88,1.04	0.32
	3	0.86	0.80,0.92	<0.001
> 24 months	1	1.00		
	2	1.05	0.96,1.15	0.27
	3	0.97	0.89,1.06	0.50

*Handwash group 1 = referent lowest compliance (< 25%) for 8 centres
Handwash group 2 = moderate compliance (25 -69%) for 8 centres
Handwash group 3 = high compliance (> 70%) for 7 centres
† Standard Error adjusted for clustering by centre

Table 7.19 Relative risk (RR) of cold (relative to lowest compliance) after adjusting for confounding variables and clustering by centre for three groups of nose wiping compliance among intervention centers, by age group

Age Group	Nose wipe Group *	RR	Robust† 95 % CI	Robust† p value
<= 24 months	1	1.00		
	2	0.98	0.90,1.06	0.64
	3	0.90	0.82,0.99	0.03
> 24 months	1	1.00		
	2	0.99	0.86,1.13	0.95
	3	0.95	0.84,1.08	0.46

* Nose wipe group 1 = referent lowest compliance (<10%) for 8 centres
Nose wipe group 2 = moderate compliance (10-96%) for 8 centres
Nose wipe group 3 = high compliance (97-100%) for 7 centres
† Standard Error adjusted for clustering by centre

Child absence from child care with a cold

A day that a child was absent from care with an upper respiratory infection was defined by the report of:

1. absence from child care because of illness,
2. a day with symptoms that met the criteria of a new cold, and
3. no report of diarrhoea.

The incidence of these absent days with a cold was seven per child year in control centres and six per child year in intervention centres (Table 7.20).

Table 7.20 Incidence of absence from child care with an upper respiratory infection

Status	Number of absent days	Number of child days	Incidence per child year
Intervention	1,033	62,159	6
Control	1,014	51,518	7
Total	2,047	113,677	6.5

Multivariable analysis of the impact of the intervention on absence with upper respiratory infection days, after adjusting for confounding revealed a reduced risk of absence in both age groups in intervention centres. However, neither result is statistically significant (Table 7.21).

Table 7.21 Relative risk (RR) of days absent from child care with a cold after adjusting for confounding and clustering by centre

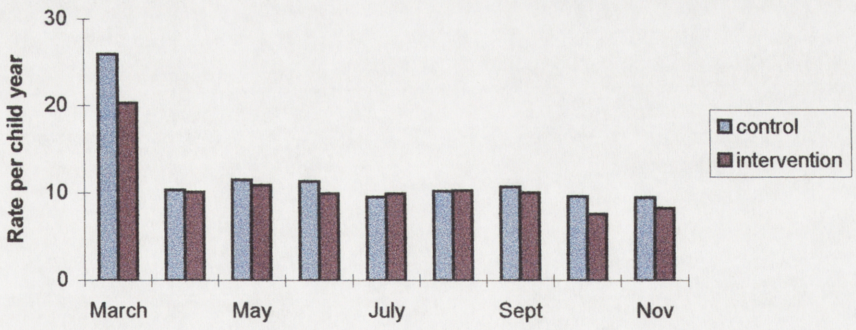
Age	Relative Risk	Robust* 95 % CI	Robust* p value
<=24 months	0.89	0.65,1.21	0.45
>24 months	0.78	0.55,1.11	0.18
All	0.85	0.66,1.08	0.19

*Standard Error adjusted for clustering by centre

Rate by month and comparison with surveillance of respiratory viruses

The rate of cold in intervention and control centres in each month of 1996 is presented in Figure 7.1. There is an apparent higher rate in March compared with other months of the year. This higher reporting of illness in March was also present in the reports of diarrhoea (Chapter 8). I consider that the higher rate of illness reported in the first month of March is misleading. As noted in the previous chapter, there were fewer days of reporting by parents in March than in other months of the year: there were approximately 4,000 days of child surveillance in March compared with 14,000 for each month from April to October and 9,000 in November. The high rate in March may be a result of the smaller denominator or could represent bias from early enrolment by parents of children who were unwell or enthusiastic reporting of illness in the first telephone call.

Figure 7.1 Rate of cold per child year by month



The reduction in colds that was shown to be significant in children aged 24 months or under in intervention centres can be seen in Figure 7.2. A lower rate of colds was present in intervention centres compared with control in the months of March, May, June, October and November 1996. In contrast, there was little difference in the rate of cold for each month in children over 24 months of age in intervention compared with control centres (Figure 7.3).

Figure 7.2 Rate of cold per child year by month in children 24 months of age or under

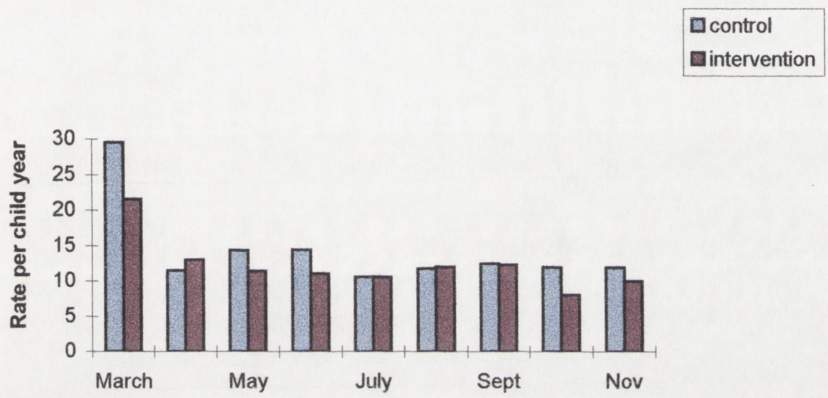
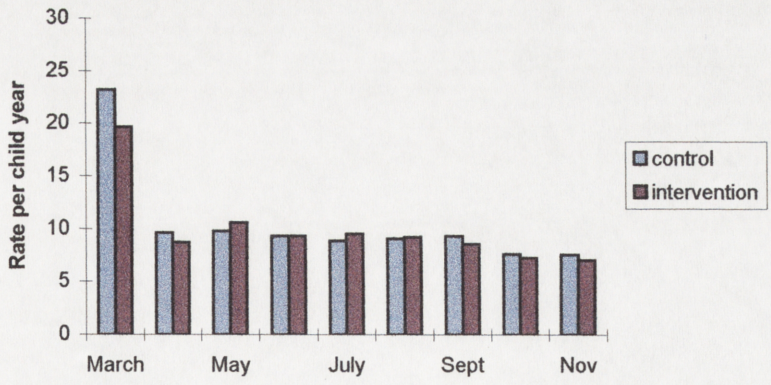


Figure 7.3 Rate of cold per child year by month in children over 24 months of age



The lower rate of cold in younger children in intervention centres in certain months of the year raises the question of whether the intervention reduced transmission of particular respiratory viruses that were circulating at that time. I obtained surveillance data about respiratory viruses in 1996 from the Communicable Diseases Intelligence (CDI) LabVISE scheme. This is a passive surveillance system of laboratory reports of virus isolation or detection from around Australia. To compare with the seasonal pattern in this trial, I obtained surveillance reports from the ACT and surrounding state New South Wales (NSW) laboratories. The reports from NSW were included because there were few reports from the ACT and the two areas a geographically adjacent.

The two periods of reduction of respiratory infection in young children of May/June and October/November coincide with peak periods for different respiratory viruses. In the early period of May and June, the reduction coincides with peak reports of respiratory syncytial virus, rhinovirus and parainfluenza type 1 (Figures 7.4, 7.5).

Figure 7.4 Rate of cold per child year by month in children 24 months of age or under and surveillance reports of respiratory syncytial virus (RSV) from NSW and ACT laboratories (CDI LabVISE scheme), March to November 1996

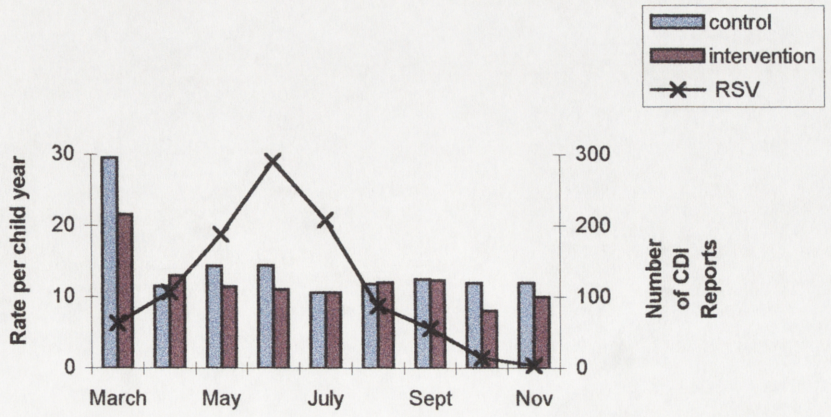
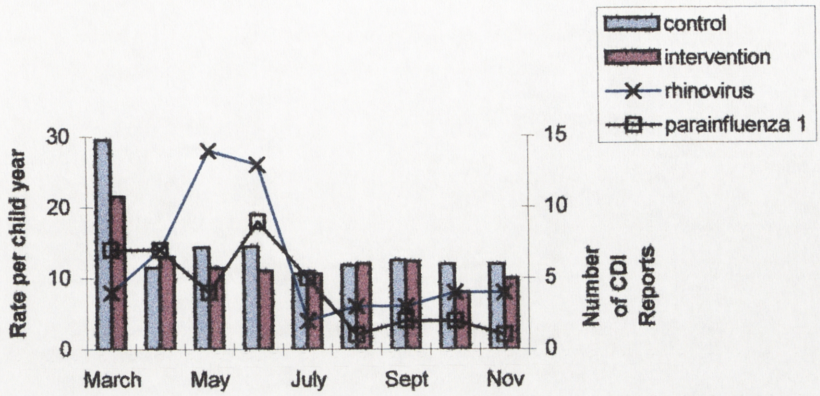
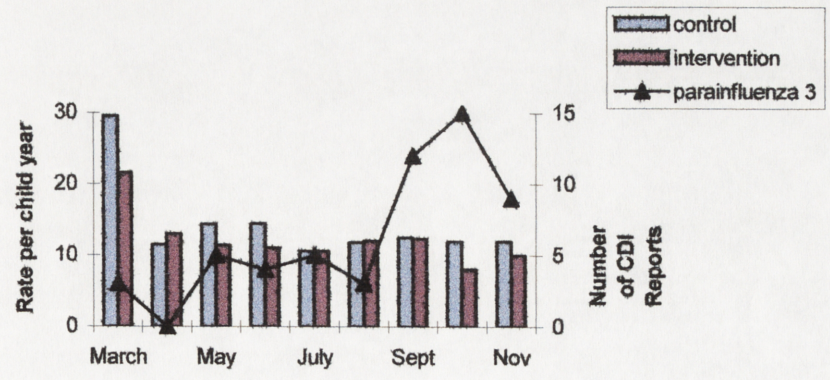


Figure 7.5 Rate of cold per child year by month in children 24 months of age or under and surveillance reports of rhinovirus and parainfluenza type 1 from NSW and ACT laboratories (CDI LabVISE scheme), March to November 1996



The reduction of respiratory infection later in the year coincides with peak reports of parainfluenza virus type 3 (Figure 7.6). Parainfluenza virus type 2 is not included in the figures because there were only two reports of isolation of this virus in 1996.

Figure 7.6 Rate of cold per child year by month in children 24 months of age or under and surveillance reports of parainfluenza 3 from NSW and ACT laboratories (CDI LabVISE scheme), March to November 1996



This comparison suggests that the intervention may have impacted on either RSV or rhinovirus or parainfluenza type 1 virus in late Autumn and early winter (May/June) and that the reduction in Spring (October/November) may be interruption of spread of parainfluenza type 3 virus. However, the CDI LabVISE surveillance scheme is limited to passive surveillance of viruses that are routinely detected or cultured in laboratories. The reduction in the intervention centres could be the result of an impact of the intervention on other viruses that cause colds but are less frequently identified and reported to the scheme, such as coronavirus. There is no apparent virus that was present in high numbers at the time of the reduction in March 1996. This may have been a period where colds were caused by another virus that is not routinely reported or may represent a reporting bias.

Sensitivity of results to a change in definition of a cold

Significant reduction of colds is not seen in the crude rates or adjusted multivariable analysis when two days of cough alone is allowable as a criterion of a cold. However, with high compliance for child handwashing, there is a significant reduction in illness in young children with this new definition. The reduction is present in both "intent to treat" and "treatment received" analyses.

Modified definition

A cold allowing cough as sole symptom was defined as:

- any two of the symptoms of runny nose, blocked nose or cough on any one day, or
- any two of the symptoms of runny nose, blocked nose or cough for two consecutive days *including* two consecutive days of cough.

The occurrence of a cold including cough as the sole symptom was classed as a new episode if the cold followed three symptom-free days.

Incidence

When cough is allowable as a sole symptom of a cold there is little difference in the crude rates between intervention centres and control (Table 7.22).

Table 7.22 Incidence of episodes of cold (including cough as sole symptom) per child per year by intervention status

Children	No. of colds allowing cough as sole symptom	No. of child days	Incidence per child year
Intervention	2,266	62,159	13.3
Control	1,964	51,518	13.9
All	4,230	113,677	13.6
Crude incidence rate ratio 95 % CI			0.96 (0.90,1.02)

Incidence by age group and sex

The crude incidence by age group again suggests that the intervention had an impact on younger children but not on those over 24 months of age (Table 7.23). There was no difference in rate ratio when stratified by sex (Table 7.24).

Table 7.23 Incidence of cold including cough as sole symptom by intervention status and age group

Age group	Status	No. of colds (cough)	No. of child days	Colds (cough) per child year	Incidence rate ratio	95 % CI
<=24 months	Intervention	876	22,620	13.8		
	Control	894	21,312	15.1	0.92	0.84,1.01
> 24 months	Intervention	1,390	39,539	12.6		
	Control	1,070	30,206	12.5	0.99	0.92,1.07
Total		4,230	113,677			

Table 7.24 Incidence of cold including cough as sole symptom by intervention status and sex

Sex	Status	No. of colds (cough)	No. of child days	Colds (cough) per child year	Incidence rate ratio	95 % CI
Female	Intervention	1,124	31,211	13.1	0.94	0.86,1.02
	Control	1000	26,084	13.9		
Male	Intervention	1,142	30,948	13.5	0.97	0.89,1.06
	Control	964	25,434	13.8		
Total		4,230	113,677			

Impact of the intervention fully adjusted

There was no impact of the intervention on risk of cold (including cough as sole symptom) in any age group after adjusting for confounding (Table 7.25).

Table 7.25 Relative risk (RR) of cold (including cough as sole symptom) after adjusting for confounding, by age group

Age group	Relative risk of cold (cough)	Robust* 95 % CI	Robust* p value	Standard 95 % CI	Standard p value
<= 24 months	0.94	0.86,1.03	0.17	0.82,1.07	0.35
> 24 months	1.03	0.94,1.13	0.50	0.89,1.20	0.67
All	0.99	0.95,1.02	0.53	0.91,1.07	0.75

* Standard Error adjusted for clustering by centre

Compliance with infection control practices

Compliance, "intent to treat"

The dose response previously seen with handwashing and nose wiping compliance is present across the full age range but even with high compliance the reduction is not statistically significant (Tables 7.26 and 7.27).

Table 7.26 Relative risk (RR) of cold including cough as sole symptom (relative to control centres) after adjusting for confounding, graded by the intervention centre children's compliance with handwashing

Handwash group*	RR	Robust† 95 % CI	Robust† p value	Standard 95% CI	Standard p value
Control	1.00				
1	1.03	0.97,1.09	0.38	0.93,1.13	0.60
2	0.98	0.95,1.01	0.15	0.89,1.07	0.65
3	0.96	0.91,1.01	0.11	0.86,1.07	0.45

* Handwash group 1 = lowest compliance rate (53-69%) for 4 centres
Handwash group 2 = moderate compliance rate (70-79%) for 4 centres
Handwash group 3 = high compliance rate (over 80%) for 3 centres
† Standard Error adjusted for clustering by centre

Table 7.27 Relative risk (RR) of cold including cough as sole symptom (relative to control centres) after adjusting for confounding, graded by the intervention centre staff compliance with nose wipe method

Nose wipe group*	RR	Robust† 95 % CI	Robust† p value	Standard 95% CI	Standard p value
Control	1.00				
1	1.02	0.96,1.09	0.51	0.92,1.14	0.70
2	0.97	0.94,1.01	0.18	0.89,1.05	0.52

* Nose wipe group 1 = moderate compliance rate (87-96%) for 4 centres
Nose wipe group 2 = high compliance rate (97-100%) for 7 centres
† Standard Error adjusted for clustering by centre

Compliance, "intent to treat" by age group

The dose response effect is seen with younger children with significant reduction in colds when child handwashing compliance is high. The effect is not present in children over 24 months of age (Table 7.28 and 7.29).

Table 7.28 Relative risk (RR) of cold including cough as sole symptom (relative to control centers) after adjusting for confounding variables and clustering by centre for three groups of children's handwashing compliance among intervention centers, by age group

Age group	Handwash group*	RR	Robust† 95 % CI	Robust† p value
<= 24 months	Control	1		
	1	1.00	0.87,1.14	0.97
	2	0.94	0.82,1.06	0.32
	3	0.89	0.79,1.00	0.05
> 24 months	Control	1		
	1	1.04	0.96,1.13	0.27
	2	1.01	0.89,1.14	0.87
	3	1.04	0.96,1.14	0.32

* Handwash group 1 = lowest compliance rate (53-69%) for 4 centres
Handwash group 2 = moderate compliance rate (70-79%) for 4 centres
Handwash group 3 = high compliance rate (over 80%) for 3 centres
† Standard Error adjusted for clustering by centre

Table 7.29 Relative risk (RR) of cold including cough as sole symptom (relative to control centres) after adjusting for confounding variables and clustering by centre for two groups of nose wiping compliance among intervention centres, by age group

Age Group	Nose wipe group*	RR	Robust† 95 % CI	Robust † p value
<= 24 months	Control	1		
	1	0.95	0.83,1.07	0.39
	2	0.94	0.84,1.04	0.23
> 24 months	Control	1		
	1	1.04	0.87,1.27	0.62
	2	1.03	0.88,1.19	0.75

* Nose wipe group 1 = moderate compliance rate (87- 96%) for 4 centres
Nose wipe group 2 = high compliance rate (97 - 100%) for 7 centres
† Standard Error adjusted for clustering by centre

Compliance, "treatment received"

Across the full age range, and irrespective of randomisation, the relative risk of cold decreased as compliance with children's handwashing and nose wiping improved. However this decrease did not attain statistical significance (Table 7.30,7.31).

Table 7.30 Relative risk (RR) of cold including cough as sole symptom (relative to lowest compliance centres) after adjusting for confounding variables for three groups of children's handwashing compliance

Handwash group*	RR	Robust † 95% CI	Robust† p value	Standard 95% CI	Standard p value
1	1.00				
2	1.02	0.98,1.07	0.32	0.93,1.12	0.62
3	0.97	0.94,1.01	0.17	0.89,1.07	0.57

*Handwash group 1= referent lowest compliance (<25%) for 8 centres
Handwash group 2 = moderate compliance (25-69%) for 8 centres
Handwash group 3 = high compliance (> 70%) for 7 centres
† Standard Error adjusted for clustering by centre

Table 7.31 Relative risk (RR) of cold including cough as sole symptom (relative to lowest compliance centres) after adjusting for confounding variables for three groups of nose wiping compliance

Nose wipe group*	RR	Robust† 95% CI	Robust† p value	Standard 95% CI	Standard p value
1	1.00				
2	0.99	0.94,1.04	0.68	0.89,1.09	0.84
3	0.96	0.93,1.00	0.08	0.88,1.05	0.43

*Nose wipe group 1 = referent lowest compliance (< 10%) for 8 centres
Nose wipe group 2 = moderate compliance (10-96%) for 8 centres
Nose wipe group 3 = high compliance (97-100%) for 7 centres
† Standard Error adjusted for clustering by centre

Compliance, "treatment received" by age group

With high compliance with handwashing, the risk of cold (including cough as sole symptom) in young children is significantly decreased (Table 7.32).

Although the relative risk in young children also decreases with improved compliance with nose wiping, this is not statistically significant (Table 7.33).

Table 7.32 Relative risk of cold including cough as sole symptom (relative to lowest compliance) after adjusting for confounding variables and clustering by centre for three groups of children's handwashing compliance, by age group

Age Group	Handwash group*	RR	Robust† 95 % CI	Robust† p value
<= 24 months	1	1.00		
	2	0.97	0.88,1.06	0.50
	3	0.90	0.82,0.99	0.04
> 24 months	1	1.00		
	2	1.04	0.96,1.14	0.28
	3	1.04	0.96,1.13	0.34

*Handwash group 1= referent lowest compliance (< 25%) for 8 centres
Handwash group 2 = moderate compliance (25-69%) for 8 centres
Handwash group 3 = high compliance (> 70%) for 7 centres
† Standard Error adjusted for clustering by centre

Table 7.33 Relative risk of cold including cough as sole symptom (relative to lowest compliance) after adjusting for confounding variables and clustering by centre for three groups of nose wiping compliance among intervention centers, by age group

Age Group	Nose wipe group *	RR	Robust† 95 % CI	Robust† p value
<= 24 months	1	1.00		
	2	0.95	0.86,1.05	0.32
	3	0.93	0.83,1.03	0.19
> 24 months	1	1.00		
	2	1.01	0.85,1.19	0.95
	3	1.01	0.86,1.12	0.86

*Nose wipe group 1 = referent lowest compliance (<10%) for 8 centres
Nose wipe group 2 = moderate compliance (10-96%) for 8 centres
Nose wipe group 3 = high compliance (97-100%) for 8 centres
† Standard Error adjusted for clustering by centre

Discussion

Acute respiratory infections were reduced in younger children by 10 per cent (Table 7.11, RR 0.90, 95% CI 0.83,0.97 p=0.01). This reduction by the intervention which aimed to reduce hand and fomite contamination with respiratory viruses supports the theory that direct transmission of colds is important in children in child care.

The ability of the techniques to reduce episodes of colds in children in child care was limited to young children 24 months of age or under. There are some possible reasons for an impact only in this age group. In a longitudinal study, Wald et al showed that in only the first two years of life do children who attend child care have an increased risk of frequent respiratory infection[65]. It is also plausible that the intervention had a demonstrable impact on the youngest children who are those least able to blow their own noses and wash their own hands.

There may be a microbiological reason that the intervention had an impact only in the young. The comparison of periods of reduction of illness with seasonal virus surveillance suggests that in May and June the intervention may have impacted on either rhinovirus, parainfluenza virus type 1 or respiratory syncytial virus(RSV). RSV infections are more common in younger children, the rate of RSV infection in the first 24 months of life is 1.5 to seven times higher than the rate in children over 24 months of age[131]. Perhaps the intervention impacted on this virus that is more common in younger children and is able to be spread by direct contact[80]. However, infection was also reduced later in the year at a time when parainfluenza type 3 virus was prevalent. Without documentation of respiratory viruses in this trial I am unable to determine if the reason for the intervention only impacting on young children is due to an impact on particular viruses.

The was a clear dose response effect of two aspects of the infection control intervention, nose wiping and child handwashing. As implementation of the practices improved the reduction in illness was greater. However, to have an impact in young children, infection control techniques needed to be used consistently. Implementing recommended handwashing less than 70 per cent of the time had no impact on infection at all, and recommended nose wipes needed to be performed at least 97 per cent of the time to reduce infection. It may be that these two measured infection control procedures may not be responsible alone for reducing illness. They may be markers of general good performance of infection control including techniques not measured in the observations but implemented in the trial, such as daily washing of toys.

The pattern of reduction of illness in young children is present even with a modified case definition. I devised the definition for a cold before I commenced analysis of the data and did not accept that two days of a cough with no other respiratory symptom represented an acute respiratory infection. Two days of coughing with no other symptom was more likely to represent an episode of asthma. Some may argue that if two days of runny nose or blocked nose alone were accepted as a definition of cold then so too should two days of a cough. Because of this, I reanalysed the data after redefining a cold including the two days of cough. Although there was no reduction in episodes of cold (including cough alone) in children of either age group, when graded by compliance with children's handwashing, compliance of over 80 per cent did translate to a significant reduction in colds (including cough alone) of 10 per cent in children 24 months of age or under. I maintain that this definition does not accurately reflect a cold. However, even with this definition, the pattern of a reduction of illness in young children was again shown when compliance was high.

Apart from reducing child morbidity, there are other likely effects of this intervention on secondary illnesses for families as young children frequently introduce respiratory infections to a household[132]. I was unable to measure secondary infections in this trial. Although reduction in respiratory illness in this setting did not translate to a significant reduction in absence from child care, this

is consistent with practice in Australia where children with upper respiratory infection are rarely kept away from care.

This intervention has the potential to make a large impact on acute respiratory infection in children in child care. When compliance with handwashing was high (over 80 per cent) the reduction of respiratory infections in young children was 17 per cent (Table 7.14, RR 0.83, 95%CI 0.76,0.90 p<0.001). In 1996, 82,600 Australian children 24 months of age or under attended long day care centres[130]. With an incidence of respiratory infection of 13 per child year (control children Table 7.3), these children suffer from 1,073,800 colds per year. With this intervention and high compliance within child care, a reduction of 17 per cent of colds translates to preventing 182,546 of these infections each year.

Chapter 8 Conclusion

Recommended infection control practices were implemented in intervention centres

The first phase of the research question was whether training of child care staff resulted in the performance of recommended practices of infection control. Infection control practices were significantly better performed in intervention centres than in control centres throughout the entire trial. Adherence to each of the four categories of: recommended handwashing for children, recommended handwashing for staff, use of a barrier on the change mat, and a recommended nose wipe, was over 70 per cent in intervention centres. These practices were infrequently performed in control centres, ranging from only three per cent for recommended staff handwashing to 30 per cent for use of a disposable barrier on the change mat.

With the exception of the nose wiping technique, the practices included in the training were not entirely new. Applying appropriate practices to routines in centres is challenging, even though these are described in *Staying Healthy in Child Care*, a book that was available in every centre for all staff to read. Part of the success of this trial's implementation of the practices is attributable to having held the training within the staff's own child care centre. This enabled the staff and trainer to discuss their routines with their colleagues, and to be creative in considering ways to apply the principles in their own circumstances. One training session was enough to institute change: in control centres every practice improved after training.

Reinforcement of training is clearly important. The high turnover of staff in child care centres makes it difficult to maintain consistent practices over time.

Deterioration in performance in intervention centres was seen six months after the trial; it was present in all practices other than nose wiping. The high staff turnover is not the only limiting factor to infection control standards in child care. Budget constraints limit both the use of consumable items and the correction of physical inadequacies in centre facilities such as poor access to warm running water. There was no financial assistance to any of the child care centres in the trial, either for paying staff to attend training or for consumable items. So despite the economic obstacles, these practices were instituted in normal child settings. This is important when considering the cost of applying the intervention in other centres in Australia. We identified inexpensive alternatives to traditional infection control aids. However, one obstacle not readily amenable to change was the quality of bathroom facilities. In some centres children could not access warm water to wash their hands and babies could rarely access running water at all. Newly constructed child care centres need at the least, low to the ground sinks with motion-sensor operated taps, warm running water, and a narrow basin that allows a child to reach the water in every child care room. An ideal sink for babies to use would have a built-in, non-slip seat that could support a baby while their hands were washed by staff. In the established facilities in this trial, a high chair attached to or near a sink that supported the child's weight aided handwashing as did the metal frame that attached to the sink designed by one director.

The infection control practices successfully reduced acute infections

Acute diarrhoea

A substantial and significant reduction in episodes of acute diarrhoea was attained in children over 24 months of age. The risk of diarrhoea was 52 per cent lower in older children in intervention centres than in control centres. The reduction was even greater when children's handwashing met over 80 per cent compliance: a 66 per cent decrease. However, there was not a significant

reduction in episodes of diarrhoea in younger children, 24 months of age or under. Their risk of diarrhoea decreased with each level of improved compliance with child handwashing; but even with high compliance, the decrease was not statistically significant.

There are plausible reasons for there being a different impact on older children compared with younger children. Different pathogens are prevalent between age groups, and these may be differentially affected by hand and fomite contamination. It would have been an advantage if I had been able to measure the pathogens in unwell children throughout the trial, but this was beyond my resources. Children's behaviour may be another reason why the intervention reduced diarrhoeal illness only in older children. Older children's toileting behaviour may give them a different opportunity for exposure to organisms. Older children may be alone when they use a toilet so it was important that the handwashing routine was an accepted routine for older children. This acceptance was facilitated by the use of nursery rhyme songs and by children's propensity to cling to routine. The recommended washing of children's hands may have reduced the transmission of organisms from child-to-child and the spread of organisms from a child to the environment. Perhaps in the older age group there was an excess rate of disease that was more amenable to interruption of child to child transmission than in the younger age group.

Acute respiratory infection

Acute respiratory infection was also reduced in children in intervention centres but in contrast to diarrhoea this reduction was seen only in younger children (24 months or under). This is the first report of a successful reduction of respiratory infection in a community intervention trial by practical methods. Although interruption of the transmission of colds has been attained in experimental settings, translation of practical methods to community settings has not been effective[101-109].

In children 24 months of age or under, colds were significantly reduced by 10 per cent. There was a dose response effect where the improvement of infection control practices, measured by children's handwashing or nose wiping technique, translated to a greater reduction of illness. When compliance with children's handwashing was over 80 per cent, colds in children in intervention centres were significantly reduced by 17 per cent compared with children in control centres.

Why should the intervention have impacted on colds only in younger children? Wald et al showed that it is only in the first two years of life that children in child care centres have an increased risk of respiratory infection compared with children at home[65]. It may be that the rate of infection in older children 24 months and over (9.4 per child year) is the unavoidable rate that occurs in all children. It is also possible that children over 24 months of age have more contacts, and opportunities for exposure to infection, outside their child care centre than younger children. Infections acquired outside the centres could not have been reduced by this intervention. Because not all respiratory viruses may be transmitted in the same manner, another reason may be that the intervention, that affected only direct transmission, was more effective at preventing the transmission of organisms present in young children than those that were causing illness in older children.

The impact on families

Absence from child care

Absence from child care from both acute diarrhoeal and respiratory illness was lower in children in intervention centres; however neither reduction was statistically significant. Absence with diarrhoea was close to significance (RR 0.54, 95 % CI 0.28,1.07, p = 0.07), and the suggested reduction of 46 per cent was consistent with both the reduction in diarrhoea and with child care centre policies of excluding children with diarrhoea. Children's absence from child care

has a high impact on families. Parents who are working need either to find alternative care for their child or to be absent themselves from a day at work.

Secondary infection

I did not measure the impact of the reduction of illness in children in child care on secondary infections in families. Certainly others have shown that families of children in child care are at risk of diarrhoea, and that children are most likely to be the family member who introduces a respiratory infection into a home[17,132]. Given this, in the population under study the impact on illness in the home may have been substantial.

Infection control practices

What reduced infection?

Which particular infection control practices reduced infection in children cannot be determined from this work. I believe that the grading of compliance for performance of the infection control practices represents overall compliance with all facets of the intervention. There were other practices, such as the daily washing of toys and the altering of nappy changing and food routines, that were implemented but not measured in the observations. Handwashing or nose wiping may therefore be proxy measures of other practices.

Level of compliance needed to obtain the impact

The greatest reduction of illness with both diarrhoeal and respiratory infections was seen with the highest compliance. However, the level of compliance that was needed to attain a reduction was different between the two illnesses. A reduction of 57 per cent of diarrhoeal illness was attained in older children when

compliance with children's handwashing was only 53 to 69 per cent. Diarrhoea decreased by another nine per cent when compliance rose to 80 per cent. In contrast, there was no reduction in respiratory infections in younger children when handwashing compliance was between 53 and 69 per cent. However, an increase in compliance between to 70 and 79 per cent attained a nine per cent reduction in respiratory infections, and a compliance of 80 per cent attained the maximal reduction of 17 per cent.

Limitations

There were some limitations to this work. The parents were not blind to the intervention status of their child's centre. Although I did not inform the parents of their centre's role in the trial, they may have determined this from the centre or it's staff. I consider this limitation was unavoidable because it was impossible and unethical to prevent parents from having contact with their child care centre and staff. The families in this trial had a higher income, more frequently had two parents in the home and spoke English at home than their Australia-wide counterparts. Could this affect the generalisability of the work? The intervention did not depend upon any compliance within the home and thus these factors have little impact on the intervention. However it remains possible that children from less advantaged homes may attain less benefit from the intervention than the children in this trial.

Selection bias may have occurred when parents were recruited for the trial as recruitment depended upon the cooperation of the child care staff. In retrospect I would have preferred to have had a longer time for recruitment and to have avoided the need to involve staff in this process. Out-migration of children may also have introduced a selection bias, if the migration was related to illness. I did not anticipate the drop-out rate that occurred in this trial, yet it was not foreseeable. In the years preceding 1996, child care centres in the ACT had waiting lists for care positions, and vacant positions were extremely rare. In 1996, when a downturn in employment occurred in the city, centres were unable

to fill vacant positions and some closed. I was only able to determine each child's reason for leaving their centre for 47 per cent of dropouts. Only one child left for health reasons. Obtaining the reasons for all children leaving their child care would have excluded potential selection bias.

There are other methods within the trial that I now consider would have been advantageous. I provided the calendars for parents as a simple prompt for telephone interviews. However, the calendars represented valuable information that I could have used to validate the records from Datacol Research. In retrospect I would have organised to collect a sample of calendars for this purpose. Another factor that I did not measure was whether a child attended care full time or for three or four days per week. Although I asked this question on the children's health and home life questionnaire, it became apparent as the trial progressed that this was not an accurate reflection of children's attendance. Children frequently changed their care arrangements from three to five days per week, depending on their parents' needs. I was not able to determine whether attending full time or for three or four days had a different impact on the children's illness. I did ensure that children remained eligible to participate in the trial by attending their centre for at least three days per week repeatedly throughout the trial. However, it would have been easy to have added a question to each interview about the number of days that the child attended child care in the previous two weeks.

I recognised at the outset that determining which organisms were causing infections in children throughout the year, and thereby estimating those affected by the intervention, was beneficial. However, I also realised that I could not collect children's specimens alone, and that I would need much greater funding to cover the costs of the tests and a research assistant, than I could reasonably hope to attain. Nonetheless, given the differential impact of the intervention on age groups, I would now greatly value having information about which organisms were causing illness.

The future

Other options for the control of communicable diseases in child care

There are possible methods of limiting communicable disease spread in child care that have not been tested to date. One involves the limiting of group size. Although this method could theoretically reduce disease, it is difficult to imagine how without assistance child care centres could afford to operate with smaller groups. Smaller groups would require larger staff numbers. Another method suggested by some for the control of disease is cohorting of children with the same illness together. However, there are logistic and ethical difficulties with cohorting.

Is there a need for control of communicable diseases in other child care settings?

The risk of communicable diseases in other child care settings is not well understood. It is important to know the incidence of communicable diseases in children who attend other forms of child care, such as day care homes (care in the carer's home) or occasional care centres. If the incidence is high, are similar interventions relevant for such settings?

Evidence based public health practices

This trial provides the evidence that training for child care staff can improve infection control practices, and that these practices reduce the incidence of common infections in children in child care. Because the impact of the intervention was seen in both age groups, in respiratory infections in younger children and diarrhoeal infections in older children, the training needs to be applied for child care workers who care for children of all ages. In this trial I obtained a high compliance from child care workers without being able to give them any evidence that the practices reduced illness. Compliance by workers may

now be even easier to attain because of the evidence that the practices reduce infection.

Distributing the results of this trial to those who need to know and establishing training for child care workers across Australia

I intend to disseminate the information from this trial to child care workers and to the Child Care Branch of the Commonwealth Department of Health and Family Services, a key government body for child care practices. I shall prepare plain English publications for workers and present the work to peak representative groups in child care. Using the evidence I hope to be able to influence government policy to establish appropriate regular training for all workers in child care centres.

In conclusion, implementation of this infection control program with high compliance in child care centres could, if my findings are generalisable, prevent in one year:

- over 180,000 episodes of colds in Australian children aged 24 months of age or under, and
- over 120,000 episodes of diarrhoea in Australian children aged over 24 months.

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Appendices

Appendix 1 Ethics committee approval

THE AUSTRALIAN NATIONAL UNIVERSITY

ETHICS IN HUMAN EXPERIMENTATION COMMITTEE

Outcome of consideration of Protocol

Protocol No. M9601 **Date of Submission: 22 January 1996**

Project Title:	**Impact of infection control intervention on the incidence of diarrhoea and respiratory infection in children who attend long day care centres in the ACT - Version 2 -**

Submitted by: **Dr Leslee Roberts**

On behalf of the Ethics in Human Experimentation Committee,

I approve/do ~~not approve~~ the above protocol.

Approval is subject to the following conditions:

.....

.....

.....

Reasons for non-approval: .....

.....

.....

.....

Review due: .....

Chairperson: F. L. Jones **Date:** 7/2/96

(Professor F. L. Jones)

Appendix 2 Letter of funding offer

MINISTER FOR HUMAN SERVICES AND HEALTH
Minister Assisting the Prime Minister
for the Status of Women

Parliament House
Canberra ACT 2600

Telephone (06) 277 7220
Facsimile (06) 273 4146

- 4 JAN. 1996

Dr L Roberts
National Centre for Epidemiology
and Population Health
Australian National University ACT 0200

Dear Dr Roberts

I am pleased to advise you that I have approved a Health and Human Services Research and Development Grant of $68,888 to support the first year of your project, *Effect of Infection Control Intervention on the Incidence of Diarrhoea and Respiratory Infection in Children who Attend Child Care.*

Officers of my Department will contact you soon to inform you of any special conditions and the administrative arrangements covering the acceptance and management of the grant.

I wish you well with your project and look forward to a successful outcome.

Yours sincerely

Dr Carmen Lawrence

Appendix 3 Recruitment letter

Dear Parent,

I am writing to ask for your help in a research project about children's health.

I am studying spread of infections between children who attend child care centres in the ACT. The aim of this trial is to test ways that we may interrupt the spread of infections in child care centres. To test if these methods work I need information from parents about their child's health.

Would you be willing to help? I am asking for help from parents whose child or children were under 4 years of age at the 1st of January 1996 and who attend this child care centre for at least 3 days a week. In April you would be asked to complete a questionnaire about your child. Between March and November we would telephone you every two weeks to ask whether your child has had any infections. The telephone call would be about two minutes long if your child had been well, and about eight minutes long if your child had not been well. The information that you provide will be kept strictly confidential and used only in the preparation of statistical reports in which you will not be identified.

I am a medical practitioner, registered in the ACT, and I have qualifications in infectious diseases and public health. In recent years I worked for the National Health and Medical Research Council to produce a book called " Staying Healthy in Child Care". I have also helped staff in Children's Day Care Services, Children and Youth Services Bureau of the ACT government.

If you can help us please complete the enrolment form as soon as you can and return it to the centre. If you cannot help please return the form anyway with a brief note. Booklets providing more detail about the study are available in your centre, if you would like to discuss the study please contact me by telephone on 0414 247187. I look forward to hearing from you soon.

Thank you for your help.
Yours sincerely,

Dr Leslee Roberts

B Med (Newc), MAE

February 1996

Enrolment Form

I have read the information sheet concerning *The Child Care Communicable Diseases Trial : Interrupting Spread of Infections.*

I would like to participate in the study. All information I provide will be held in confidence by Dr Leslee Roberts. My role will be to be interviewed by telephone every two weeks and to complete a questionnaire about my child's health and home life.

I understand that I may withdraw from this study at any time.

Parent's/ Guardian's name .....

Relationship to child mother / father / other .....

Address .....

.....

Telephone number (evenings).....

Telephone number (day).....

Child's name .....

Child's sex Male / Female

Child's Date of Birth ...../...../.....

Child Care Centre .....

Room .....

How many days a week does your child attend this centre? .....

Signed Parent/ Guardian.....

Date ...../...../.....

Appendix 4 Sample calendar for parents

The Child Care Communicable Diseases Trial

Dr Leslee Roberts NCEPH ANU 2492378 & Datacol Research 2575700

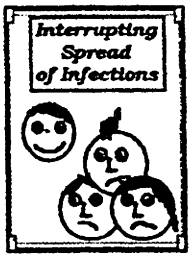
March 1996

R = Runny nose **B** = Blocked nose **C** = Cough
D = Diarrhoea *(Two or more loose or unusually watery bowel motions in 24 hours)*
Dr = Child saw a Doctor **A** = Child was Absent from Child Care
Mw = Adult Missed a Day of Work to Care for Unwell Child
P = Paracetamol **Ab** = Started an Antibiotic **Cm** = Medicine for Symptoms of a Cold

Sun	Mon	Tues	Wed	Thu	Fri	Sat
31					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18 Canberra Day	19	20	21	22	23
24	25	26	27	28	28	30

Appendix 5 Training program

The Child Care Communicable Diseases Trial



Dr Leslee Roberts
National Centre for Epidemiology and Population Health ANU

Why have *The Child Care Communicable Diseases Trial*?

Infections in child care
Methods to interrupt spread of infections
Do they work ?
How can we know ?

How are infections spread?

Respiratory Droplets, Direct contact
Indirect contact, Faecal Oral, Blood born.....

To spread infection germs need to get:
1. OUT of one person
2. INTO another person
3. SURVIVE the TRIP!
4. MULTIPLY make them sick.

Handwashing

On arrival
Before eating
After toileting/nappy changing
After touching a nose
Before going home
Before going to work in another room

Gloves

Handwashing method

Liquid soap and running water
Include back of hands, between fingers, around nails, wrists count to ten
Rinse and count to ten
Turn off the tap with paper towel
Dry hands with paper towel

Cleaning and Disinfectants

Cleaning
detergent, water and colour coded sponges, physical "disinfection"

Do Disinfectants Disinfect?
clean surfaces
enough time
adequate concentration

Interrupting Spread of Colds

Don't let viruses survive the trip

Tissues not handkerchiefs

Wash hands of "runny nose children"

Use a Toy Sin Bin and use dishwasher to wash am and pm toys

Program interrupting spread " put your finger on your nose ..... that's where your virus grows"

Manage your own hands .....

Interrupting Spread of Colds

Don't let viruses survive the trip

No touch nose wiping

Cover hands with something quick, effective and disposable .....
SANDWICH BAG

Interrupting Spread of Vomiting and Diarrhoea

Out of one person - bowel motions

Interrupt ... nappies, potties, toilets <u>hands</u>

Into another person - through the mouth

Interrupt ... clean toys and other mouth objects, <u>hands</u>

Survive the trip - good survivors

Interrupt ... clean toilet, nappy area, <u>hands</u>

Interrupting Spread of Vomiting and Diarrhoea

Careful Nappy Changing
Careful Toileting and Potty Training
Careful Handwashing

Think Outbreak

Careful Nappy Changing

Paper Barrier (& gloves if dirty)
Remove the child's clothes and nappy
Clean the child
Remove the paper barrier
Remove gloves (peel back)
Dress & wash the child's hands
Clean the table
Wash your hands

Careful Potty Emptying

are they worth it?

Wear gloves, empty contents into toilet
Rinse potty with water empty into toilet
Wash all part of the potty with soap and water, empty soapy water into the toilet
Rinse again empty into the toilet
Spray with fresh bleach solution
Air dry (out of use for half an hour)
Remove gloves, wash the sink
Wash your hands

Cleaning and Disinfectants

Fomites

1. toilets, nappy tables, sinks and taps
2. toys, toys, toys
3. benches, door handles
4. mattresses, linen, floors

Disinfectants

Quaternary ammonium compounds (quats)

do not use with soap, OK for bacteria,

not OK for viruses (colds, diarrhoea, hand foot mouth, conjunctivitis) or fungi (thrush)

Bleach

inactivated by protein, 1/10 dilution bleaches

must be fresh, OK against nearly all organisms

Phenolic

bacteria OK, not OK for viruses

Alcohol

OK with some viruses and some bacteria

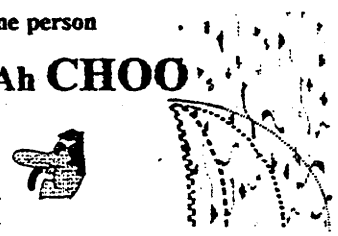
Spread of The Common Cold

rhinovirus, RSV, parainfluenza

1. OUT of one person

Ah Ah Ah Ah **CHOO**

Drip...

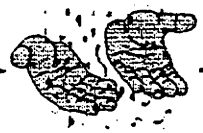


Spread of The Common Cold

2. INTO another person

By Hand

Tissue
Hand
Forearm
Toys



Nose
Eye

By Air

Spread of The Common Cold

respiratory syncytial virus

Cuddlers Touchers Sitters Study

Cuddlers - hands and breathe large and small particles ☑

Touchers - hands ONLY ☑

Sitters - breathe small particles ONLY **NO**

Wiping Noses

Toddler Room with 12 children
6 have colds

Wipe each nose 3 times an hour
= 18 wipes per hour

7 hour day - 126 nose wipes per day
2 staff = 63 nose wipes each!!

Interrupting Spread of Vomiting and Diarrhoea

THINK OUTBREAK

Record cases

Talk about interrupting spread

Program around the outbreak

Handwashing, cleaning, disinfectants

Disposable nappies

Exclusion to protect others

? "contained poo"

{Nappy changers are not food servers}

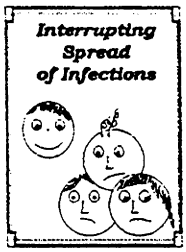
The Child Care Communicable Diseases Trial

will test interrupting spread of infections

Interrupting spread using:

daily program, handwashing, no touch routines, barrier protection of hands, cleaning, toy cleaning, the toy sin bin and "Think Outbreak"

The Child Care Communicable Diseases Trial Newsletter



Issue 1

Purpose

This newsletter will be produced every fortnight to share ideas between all active centres in the trial. One copy will be available for each room in each active centre, if you would like more copies let me know. Leave your ideas for how you have approached interrupting spread of infection in your communication book and I will include them in the newsletter. Also leave your questions as we will have a section for questions each newsletter. If you can, please suggest answers and leave them in your communication book.

Arrival Handwashing

At least SIX of our centres have been able to wash their children's hands on arrival! Very Impressive - Some parents are helping too.

Sandwich Bags

The no- name ones are about 60 cents for 150. They come in a plastic bag which tapes just as well to the tissue box.

"Home made" liquid soap

Lyn from Nan's Child Care has created their own liquid soap and is using it successfully in all rooms. They report that it dries out your hands less than commercial liquid soaps, and it is much cheaper. The recipe is:

1 cup Lux soap flakes

5 litres HOT water (boiled would be best)

1 bottle of glycerine

Shake well and dispense into individual pump containers.

I have estimated the cost per 5 litres is $1.37. Some people have reported that "Slime" will give skin reactions, this soap appears not to and I suspect it is because the concentration of soap is much lower than in slime.

Blinky Bill are using empty large sunblock containers for dispensing soap in each room.

Turning off Taps

A few people have come up with good alternatives for paper to turn of taps; 1/4 pieces of paper towel to save on paper, computer paper cut into 1/4 pieces again to save paper and cost and interleaved toilet papers in a baby wipes container.

Preschoolers in two centres have learnt to reach for a piece of paper to turn off taps!

Washing Toys

Cathy from Curtin has found a great FAST way to wash toddlers toys. She puts the toys into "toy

tidy bags" (made of open weave material like orange bags), she then squirts in some detergent and takes the bags out to the clothes line and hangs them up. With the **hose** she sprays them well and then leaves them out to dry. Make sure you spray both sides. Great stuff!

Songs, Songs, Songs

To the tune of "Here We Go Round the Mulberry Bush"

This is the way we wash our hands
action (palms together)
Wash our hands wash our hands
action (1 palm on top of the back of the other hand , fingers down in between each other)
This is the way we wash our hands, early in the morning.
This is the way we wash our fingers.....
This is the way we wash our wrists.....

Danielle and Tracey, Bambi Child Care

A wash wash wash

To the tune of "A Ram Sam Sam"
A rub scrub scrub
A rub scrub scrub.
Washy Washy Washy Washy
Rub Scrub Scrub

Gail, Margaret and Simone, Chifley Child Care

Scrub Scrub Scrub

Scrub Scrub Scrub your hands
Scrub your hands this way
Scrub, scrub, scrub your hands
Scrub your hands this way
Rinse,rinse, rinse your hands
Rinse your hands this way,
Rinse, rinse, rinse your hands
Rinse the germs away.

Suzanne, Chifley

Wash your dirty hands

Wash your dirty hands, wash your dirty hands
Rub and scrub and rub and scrub and wash your dirty hands
Wash your dirty hands, wash your dirty hands
Squelch and welch and squelch and welch and wash your dirty hands

Anonymous, Curtin Child Care

The Echo Handwash

Soap my hands, soap my hands
Give a twist, give a twist
Rub the back, rub the back
And around my wrist, and around my wrist.

Rinse my hands, rinse my hands
Up and down, up and down
Between my fingers, between my fingers
And round and round, and round and round
Dry them well and here's the trap
Dry them well and here's the trap
Careful don't touch the tap!

To the Tune of "Twinkle Twinkle Little Star":

Squirt some soap and rub it in
Don't forget to count to 10
1,2,3, 4,5,6,
7,8,9 10 is it
When the soap has done the trick
Rinse it off you won't get sick.

Veronica, Woden Campus Child Care

P.S. Have you got your nappy change mat in the sun half way through the day?

Rub and Scrub

(to your own tune!)
Rub and scrub
Rub and scrub
Rub and scrub the germs away
count to 10
because we're here all day
1,2,3,4,5,6,7,8,9..10

Anonymous, Preschool Chifley

Appendix 7 Parent two weekly telephone interview questions

Have you got (child's name) calendar there? Write response in full.

1. Has (child) had a runny nose in the last two weeks?

If yes on what calendar dates did he/she have a runny nose?

2. Has (child) had a blocked nose in the last two weeks?

If yes on what calendar dates did he/she have a blocked nose?

3. Has (child) had a cough in the last two weeks?

If yes on what calendar dates did he/she have a cough?

4. Has (child) had any diarrhoea in the last two weeks? By diarrhoea we mean two or more unusually loose ore watery bowel motions in 24 hours.

If yes on what calendar dates did he/she have diarrhoea?

5. Has he/she seen a GP or specialist in the last two weeks

If yes on what calendar dates did he/she see the doctor?

Did the doctor say (child's name) had a middle ear infection?

6. Did (child) miss any days or part days at child care in the last two weeks because of illness?

If yes on what calendar dates did he/she miss child care because of illness?

Did you or another adult miss any days of work to care for (child) while he/she was ill?

If yes on what calendar dates did you or another adult muss days of work to care for (child) whilst he/she was ill?

7 Has (child) had any antibiotics in the last two weeks?

If yes on what calendar dates did he/she start the antibiotic?

Name of antibiotic?

8. Has (child) had any paracetamol such as Panadol or Dymadon in the last two weeks

If yes on what calendar dates did he/she have the paracetamol?

Name of paracetamol

9. Has he/she had any medicine to relieve symptoms of cold in the last two weeks?

If yes on what dates did he/she have the medicine?

Name of medicine?

10. Was (child) admitted to hospital in the last two weeks?

On what calendar date was (child) admitted to hospital?

If yes we would like to find more about his/her illness. Is it all right for Dr Roberts to telephone you at another time to talk about this?

Administration

Periodically How many days per week does (child) attend child care centre?

Interviewers subjective assessment of whether the respondent is using the calendar

1. Calendar written on
2. Calendar used as aide while speaking but not written on
3. Calendar not used
4. Can't tell

Next call date

Child ID Number

Day Number

Call Number

Date interviewed

Interviewer

Child Care Infection Control Observation Record

Centre.....

Date ...../...../..... **Signed** .....

Appendix 8 Observation form

Nappy changes	Disposable Barrier		Total	If Not able to Stand - Hands Wiped		If able to stand: Child's H/W 20 sec		Total	Removed gloves before putting child's clothes on		Total Changes where Glove/s Used	Staff Wash Hand for 20 seconds	20 sec	No HW	Total
Count	Yes	No		Yes	No	Yes	No		Yes	No		Yes	No		
Babies 5															
Toddlers 5															

Children Using Toilet

Child Used Toilet	Hands washed for 20 seconds	No HW		Total
Count	Yes	No		

Ready to Eat	Before eating child H/W 20 sec	20 sec	No HW	Total
	Yes	No		

Nose Wipe

Nose Wiped by Staff Member	protect hand or 20 sec HW	No HW	Total
Yes	No	No	

Nose Wiped by CHILD	20 sec HW	No HW	Total
Yes	No	No	

Appendix 9 Children's health and home life questionnaire

Dear Parent,

Thank you for your participation in The Child Care Communicable Diseases Trial.

To accurately determine whether we are able to reduce the number of infections that children acquire in child care we need information about your child's health and the factors that may affect it. All information you provide for this study will be kept confidential. If you have any questions or comments please do not hesitate to contact me on 0414 247 187

I would appreciate your cooperation in completing this questionnaire. The questionnaire is 9 pages long, will take you less than 10 minutes to complete and is the only questionnaire you will be asked to complete during the trial. When you have completed the questionnaire would you please return it in this envelope to your day care centre director.

Kind regards,

Dr Leslee Roberts
Principal Investigator

Please answer every question. Circle the number beside your answer.

1. What is your sex?

Please circle one number

MALE.....1
FEMALE.....2

2. What is your relationship to the child enrolled in the trial?

Please circle one number

PARENT.....1
OTHER.....2

PLEASE SPECIFY OTHER.....

3. In this child's home do you or another adult usually speak English?

Please circle one number

YES.....1
NO.....2

If no;

3.1 Please specify the language usually spoken

.....

Child's Child Care History

4. What was this child's age when she/he first attended a long day care centre?

YEARS_____ MONTHS _____

5. How many days per week does this child usually attend **the child care centre enrolled** in the trial?

_____ DAYS

For example; 3,3.5

6. In addition to this centre, does this child go to any other child care?

Please circle one number

YES.....1
NO.....2

If yes;

6.1. Does this child go to;

ANOTHER LONG DAY CARE CENTRE?.....1
OCCASIONAL CARE CENTRE?.....2
FAMILY DAY CARE HOME?.....3
OTHER CHILD CARE?.....4

Child's medical history

The questions in this section apply to the past health of your child. In general we are asking you to recall events that may have occurred several years ago. If you cannot remember, or were not living with the child during the time periods in question please indicate this by circling the number 9 for "don't know".

7. In general, would you say your child's health is? *Please circle one number*

EXCELLENT.....1
VERY GOOD.....2
GOOD.....3
FAIR.....4
POOR.....5

8. What did this child weigh when he or she was born?

Please circle one number

UNDER 1,500 GRAMS (3lbs 5 oz).....1
1,300 - 2,500 GRAMS (3lbs 5oz - 5 lbs 8 oz).....2
OVER 2,500 GRAMS (over 5lbs 8 oz).....3
DON'T KNOW.....9

9. Was this child born early, that is more than two weeks before the child was due to be born? *Please circle one number*

YES.....1
NO.....2

If yes;

9.1 How many weeks early was this child born?

WEEKS EARLY _____

10. Has this child ever been breast fed? *Please circle one number*

YES.....1
NO.....2
DON'T KNOW.....9

If yes;

10.1 Including times of weaning, what is the total time this child was breast fed?

MONTHS _____ WEEKS_____

For example 0 months 2 weeks or 6 months 2 weeks

10.2 What is the total time this child was **predominantly breast fed?** By this we mean the child was fed breast milk for more that half of the feeds of every day.

MONTHS _____ WEEKS_____

For example 0 months 2 weeks or 6 months 2 weeks

11. Did this child's mother smoke while she was pregnant with this child?

Please circle one number

YES.....1
NO.....2
DON'T KNOW.....9

In the calendar year 1995 (January to December) how much did your child suffer from the illnesses listed below?

12. Colds? *Please circle one number*

NEVER.....0
RARELY (1-2 BOUTS WITHIN 12 MONTHS).....1
SOMETIMES (2 - 8 BOUTS WITHIN 12 MONTHS).....2
FREQUENTLY (> 8 BOUTS WITHIN 12 MONTHS).....3
CONSTANTLY (MOST OF THE TIME).....4

13. Cough?

NEVER.....0
RARELY (1-2 BOUTS WITHIN 12 MONTHS).....1
SOMETIMES (2 - 8 BOUTS WITHIN 12 MONTHS).....2
FREQUENTLY (> 8 BOUTS WITHIN 12 MONTHS).....3
CONSTANTLY (MOST OF THE TIME).....4

14. Hayfever?

NEVER.....0
RARELY (1-2 BOUTS WITHIN 12 MONTHS).....1
SOMETIMES (2 - 8 BOUTS WITHIN 12 MONTHS).....2
FREQUENTLY (> 8 BOUTS WITHIN 12 MONTHS).....3
CONSTANTLY (MOST OF THE TIME).....4

15. Wheeze or Asthma?

NEVER.....0
RARELY (1-2 BOUTS WITHIN 12 MONTHS).....1
SOMETIMES (2 - 8 BOUTS WITHIN 12 MONTHS).....2
FREQUENTLY (> 8 BOUTS WITHIN 12 MONTHS).....3
CONSTANTLY (MOST OF THE TIME).....4

16. Bronchitis?

NEVER.....0
RARELY (1-2 BOUTS WITHIN 12 MONTHS).....1
SOMETIMES (2 - 8 BOUTS WITHIN 12 MONTHS).....2
FREQUENTLY (> 8 BOUTS WITHIN 12 MONTHS).....3
CONSTANTLY (MOST OF THE TIME).....4

17. Tonsillitis?

NEVER.....0
RARELY (1-2 BOUTS WITHIN 12 MONTHS).....1
SOMETIMES (2 - 8 BOUTS WITHIN 12 MONTHS).....2
FREQUENTLY (> 8 BOUTS WITHIN 12 MONTHS).....3
CONSTANTLY (MOST OF THE TIME).....4

18. Bronchiolitis?

NEVER.....0
RARELY (1-2 BOUTS WITHIN 12 MONTHS).....1
SOMETIMES (2 - 8 BOUTS WITHIN 12 MONTHS).....2
FREQUENTLY (> 8 BOUTS WITHIN 12 MONTHS).....3
CONSTANTLY (MOST OF THE TIME).....4

In the calendar year 1995 (January to December) how much did your child suffer from the illnesses listed below?

19. Pneumonia? *Please circle one number*

NEVER.....0
RARELY (1-2 BOUTS WITHIN 12 MONTHS).....1
SOMETIMES (2 - 8 BOUTS WITHIN 12 MONTHS).....2
FREQUENTLY (> 8 BOUTS WITHIN 12 MONTHS).....3
CONSTANTLY (MOST OF THE TIME).....4

20. Croup?

NEVER.....0
RARELY (1-2 BOUTS WITHIN 12 MONTHS).....1
SOMETIMES (2 - 8 BOUTS WITHIN 12 MONTHS).....2
FREQUENTLY (> 8 BOUTS WITHIN 12 MONTHS).....3
CONSTANTLY (MOST OF THE TIME).....4

21. Sore throat?

NEVER.....0
RARELY (1-2 BOUTS WITHIN 12 MONTHS).....1
SOMETIMES (2 - 8 BOUTS WITHIN 12 MONTHS).....2
FREQUENTLY (> 8 BOUTS WITHIN 12 MONTHS).....3
CONSTANTLY (MOST OF THE TIME).....4

22. Thick nasal discharge?

NEVER.....0
RARELY (1-2 BOUTS WITHIN 12 MONTHS).....1
SOMETIMES (2 - 8 BOUTS WITHIN 12 MONTHS).....2
FREQUENTLY (> 8 BOUTS WITHIN 12 MONTHS).....3
CONSTANTLY (MOST OF THE TIME).....4

23. Earache?

NEVER.....0
RARELY (1-2 BOUTS WITHIN 12 MONTHS).....1
SOMETIMES (2 - 8 BOUTS WITHIN 12 MONTHS).....2
FREQUENTLY (> 8 BOUTS WITHIN 12 MONTHS).....3
CONSTANTLY (MOST OF THE TIME).....4

24. Discharging ear?

NEVER.....0
RARELY (1-2 BOUTS WITHIN 12 MONTHS).....1
SOMETIMES (2 - 8 BOUTS WITHIN 12 MONTHS).....2

FREQUENTLY (> 8 BOUTS WITHIN 12 MONTHS).....3
CONSTANTLY (MOST OF THE TIME).....4

25. Middle ear infection?

NEVER.....0
RARELY (1-2 BOUTS WITHIN 12 MONTHS).....1
SOMETIMES (2 - 8 BOUTS WITHIN 12 MONTHS).....2
FREQUENTLY (> 8 BOUTS WITHIN 12 MONTHS).....3
CONSTANTLY (MOST OF THE TIME).....4

26. Does this child have grommets in his/her ears? (Grommets are small tubes that are put into a child's ear drum when a child has had many middle ear infections) *Please circle one number*

YES.....1
NO.....2
DON'T KNOW.....9

27. Has a doctor ever said that this child has asthma?*Please circle one number*

YES.....1
NO.....2
DON'T KNOW.....9

28. Has this child any chronic (long term) illness such as heart disease or cystic fibrosis? *Please circle one number*

YES.....1
NO.....2
DON'T KNOW.....9

If yes;

28.1 Please state what this illness is.

.....

..

29. Has this child ever had chicken pox? *Please circle one number*

YES.....1
NO.....2
DON'T KNOW.....9

30. Has this child ever been admitted to hospital (staying overnight in a hospital ward), other than when he/she was born? *Please circle one number*

YES.....1
NO.....2
DON'T KNOW.....9

If yes;

Please state the age of the child each time he/she was admitted to hospital and the reason for the admission . If this child has had more than six admissions to hospital please write over the page.

	AGE WHEN CHILD WAS ADMITTED TO HOSPITAL IN YEARS AND MONTHS	REASON FOR ADMISSION
Example	*0 years 6 months*	*Pneumonia*
Example	*2 years 1 month*	*Operation to put in grommets*
30.1		
30.2		
30.3		
30.4		
30.5		
30.6		

31. Does this child receive regular medicine that has been prescribed by a doctor? *Please circle one number*

YES.....1
NO.....2
DON'T KNOW.....9

If yes;

31.1 Please state the name of the medicine/s

.....

32. Does this child receive regular medicine/remedy or preventive treatment from a naturopath, herbalist or homeopath? *Please circle one number*

YES.....1
NO.....2
DON'T KNOW.....9

If yes;

32.1 Please state the name of the medicine/s

.....

..

33. Does this child receive regular medicine from another source such as over the counter medicine from a chemist? *Please circle one number*

YES.....1
NO.....2
DON'T KNOW.....9

If yes;

33.1 Please state the name of the medicine/s

.....

.....

Has this child received the following immunisations?
Please tick either the yes, no or don't know column for every vaccine. If this child has received a vaccine please write in the child's age in months when that vaccine was given. You may find it useful to use your child's personal health record book, also called the blue book.

	Vaccine	YES	AGE THE VACCINE WAS GIVEN	NO	DON'T KNOW	WAS THIS RECORDED IN THE CHILD'S HEALTH RECORD BOOK? *PLEASE CIRCLE*
34	Triple Antigen Dose 1		months			Yes No
35	Polio Dose 1		months			Yes No
36	Triple Antigen Dose 2		months			Yes No
37	Polio Dose 2		months			Yes No
38	Triple Antigen Dose 3		months			Yes No
39	Polio Dose 3		months			Yes No
40	Triple Antigen Dose 4		months			Yes No
41	Measles Mumps Rubella		months			Yes No
42	Hib *Haemophilus influenzae meningitis*		Age not required			Yes No

43. Has this child received the Hepatitis B vaccine
(This vaccine is not routinely recommended for all children)

Please circle one number

YES.....1
NO.....2
DON'T KNOW.....9

Child's home characteristics

The questions below apply to the home in which this child is currently living. If the child lives in two homes please put the answer for the home the child spends most of his/her time in.

44. How many people live in this child's home?

ADULTS 18 YEARS OF AGE AND OVER.....

CHILDREN UNDER 18 YEARS OF AGE.....

For each other child (under 18 years of age) that lives with this child, please complete the following;

	AGE OF CHILD *please write in*	SEX *please circle*		DOES HE/SHE GO TO SCHOOL? *please circle*		DOES HE/SHE GO TO CHILD CARE? *please circle*	
44.1	Years	Male	Female	Yes	No	Yes	No
44.2	Years	Male	Female	Yes	No	Yes	No
44.3	Years	Male	Female	Yes	No	Yes	No
44.4	Years	Male	Female	Yes	No	Yes	No
44.5	Years	Male	Female	Yes	No	Yes	No
44.6	Years	Male	Female	Yes	No	Yes	No

45. How many bedrooms are there in the home?

..... **BEDROOMS**

46. Are there any dogs, cats or birds at the home now?

Please circle one number

YES.....1
NO.....2

47. How is the home this child lives in heated? *Please circle one number*

NATURAL GAS.....1
ELECTRICITY.....2
OIL.....3
WOOD.....4
SOLAR.....5
LPG.....6
OTHER.....7

PLEASE SPECIFY OTHER .....

We realise there are many reasons why people smoke. For this research we do need to know about smoking as it may affect health.

48. Do you or another person in the household smoke cigarettes, pipes or cigars? *Please circle one number*

YES.....1
NO.....2

If yes;

48.1 How many cigarettes, pipes or cigars would be smoked **inside** the house in one day. Please add together all cigarettes etc smoked by each person in the household. *For example if you smoke 10 cigarettes per day inside the house and another adult smokes 30 per*

day inside, the answer would be 40 per day inside the house.

Please circle one number
FEWER THAN 10.....1
10 - 29.....2
30 - 49.....3
50 - 69.....4
MORE THAN 69.....5

We would now like to ask some questions about you.

49. How old are you?

AGE IN YEARS .....

50. At what age did you leave school?

AGE IN YEARS .....

51. Since leaving school have you obtained a trade qualification, certificate, diploma, degree or other qualification? *Please circle one number*

YES.....1
NO.....2

If yes;

51.1. Which of these groups best describes the highest qualification you have obtained? *Please circle one number*

BACHELOR DEGREE OR HIGHER.....1
TRADE / APPRENTICESHIP.....2
CERTIFICATE / DIPLOMA.....3
OTHER.....4

PLEASE SPECIFY OTHER .....

52. What is your occupation? If you work in the public service please state your position eg ASO4.

.....

We would now like to ask you some questions about your partner/spouse.

53. Do you have a partner **living in your household** with you?

Please circle one number

YES.....1
NO.....2

If no please go to question 55

54. How old is your partner?

AGE IN YEARS.....

55. At what age did he/she leave school?

AGE IN YEARS.....

56. Since leaving school has your partner obtained a trade qualification, certificate, diploma, degree or other qualification? *Please circle one number*

YES.....1
NO.....2

If yes;

56.1 Which of these groups best describes the highest qualification he/she obtained? *Please circle one number*

BACHELOR DEGREE OR HIGHER.....1
TRADE / APPRENTICESHIP.....2
CERTIFICATE / DIPLOMA.....3
OTHER.....4

57. What is your partners occupation? If he /she works in the public service please state his/her position eg ASO4.

.....

The following questions are optional.

58. In which of the following ranges did your total family income fall in the last year. *Please circle one number*

LESS THAN $ 15,000.....1
$15,000 - $29,999.....2
$30,000 - $49,999.....3
OVER $ 50,000.....4

59. Do you receive fee relief? (Child care assistance paid directly to the child care centre.) *Please circle one number*

YES.....1
NO.....2
DON'T KNOW.....9

Thank you once again for your participation in the trial.

Appendix 10 Centre Characteristics

Centre Characteristics Survey: Date .....
Centre name .....

1. Operation **Private**
Community

How many children are licensed to attend the centre? .....
How many children are enrolled currently in the centre? .....
Does the centre have a dishwasher ? **Y / N**
How is the centre heated ?
(as much detail as possible, eg central heating by natural gas with ducts in the roof)

.....
.....

Line drawing of centre layout, child care rooms, children's bathrooms

	Number of children	Age range of children	Number of staff
Nursery 1			
Nursery 2			
Little Toddlers (Tiny Tots)			
Big Toddlers			
Preschool			

Nursery 1

Nappy change area

Is this nappy change room shared with children from another room? **Y / N**

How many nappy change mats are there for nursery 1? .....

Are these nappy change mats used by children from another room? **Y / N**

Type of nappies used ?

Cloth

Disposable

Nappy cleaning : Are nappies rinsed by child care staff ? **Home nappies only/ Y / N**

Nappy cleaning : Are nappies washed by child care staff ? **Y / N**

How many sinks at adult height are there? .....

Is this/are these sinks routinely used by staff from another room? **Y / N**

Is this/are these sinks routinely used by a floater? **Y / N**

How far from the change mat is the sink where staff wash their hands?

within one metre ie. reachable arms length

one step away

more than one step away

Does the sink where staff wash their hands have hot water ? **Y / N**

Does the sink where staff wash their hands have warm mixed water ? **Y / N**

What soap is available for staff to wash their hands?

Liquid soap	***before trial***	***Liquid soap***
Bar soap		***Bar soap***
Other		***Other*** .....

What is available for staff to dry their hands?

Paper towel	***before trial***	***Paper***
Shared cloth towel		***Shared Cloth***
Individual cloth towel		***Individual towel***
Hot air dryer		***Hot air***

Is there a sink able to be reached by a baby/toddler standing on the ground? **Y / N**

Nursery 2

Nappy change area

Is this nappy change room shared with children from another room? **Y / N**

How many nappy change mats are there for children in Nursery 2? .....

Are these nappy change mats used by children from another room? **Y / N**

Type of nappies used ?

Cloth

Disposable

Nappy cleaning : Are nappies rinsed by child care staff ? **Home nappies only/ Y / N**

Nappy cleaning : Are nappies washed by child care staff ? **Y / N**

How many sinks at adult height are there? .....

Is this/are these sinks routinely used by staff from another room? **Y / N**

Is this/are these sinks routinely used by a floater? **Y / N**

How far from the change mat is the sink where staff wash their hands?

within one metre ie. reachable arms length

one step away

more than one step away

Does the sink where staff wash their hands have hot water ? **Y / N**

Does the sink where staff wash their hands have warm mixed water ? **Y / N**

What soap is available for staff to wash their hands?

Liquid soap	***before trial Liquid soap***
Bar soap	***Bar soap***
Other	***Other*** .....

What is available for staff to dry their hands?

Paper towel	***before trial***	***Paper***
Shared cloth towel		***Shared Cloth***
Individual cloth towel		***Individual towel***
Hot air dryer		***Hot air***

Is there a sink able to be reached by a baby/toddler standing on the ground? **Y / N**

Little Toddlers - Tiny Tots

Is the nappy change room shared with children from another room? **Y / N**

How many nappy change mats are there for Little Toddlers? .....

Are these nappy change mats used by children from another room? **Y / N**

Type of nappies used ? **Cloth**

Disposable

Nappy cleaning : Are nappies rinsed by child care staff ? **Home nappies only/ Y / N**

Nappy cleaning : Are nappies washed by child care staff ? **Y / N**

How many sinks at adult height are there? .....

Is this/are these sinks used routinely by staff from another room? **Y / N**

Is this/are these sinks routinely used by a floater? **Y / N**

How far from the change mat is the sink where staff wash their hands?

within one metre ie. reachable arms length

one step away

more than one step away

Does the sink where staff wash their hands have hot water ? **Y / N**

Does the sink where staff wash their hands have warm mixed water ? **Y / N**

What soap is available for staff to wash their hands?

Liquid soap	*before trial*	*Liquid soap*
Bar soap		*Bar soap*
Other		*Other* .....

What is available for staff to dry their hands?

Paper towel	*before trial*	*Paper*
Shared cloth towel		*Shared Cloth*
Individual cloth towel		*Individual towel*
Hot air dryer		*Hot air*

How many sinks where **toddlers** can reach **(without help)** to wash hands? .....

Are these reachable sinks used by children from another room? **Y / N**

Does the sink where toddlers wash their hands have warm water ? **Y / N**

What soap is available for toddlers to wash their hands?

Liquid soap	*before trial*	*Liquid soap*
Bar soap		*Bar soap*
Other		*Other* .....

What is available for toddlers to dry their hands?

Paper towel	*before trial*	*Paper*
Shared cloth towel		*Shared Cloth*
Individual cloth towel		*Individual towel*
Hot air dryer		*Hot air*

Do toddlers share toilets or potties with children from another room? **Y / N**

Big Toddlers

Is the nappy change area shared with children from another room? **Y / N**

How many nappy change mats are there? .....

Type of nappies used ? **Cloth**

Disposable

Nappy cleaning : Are nappies rinsed by child care staff ? **Home nappies only/ Y / N**

Nappy cleaning : Are nappies washed by child care staff ? **Y / N**

How many sinks at adult height are there? .....

Is this/are these sinks used routinely by staff from another room? **Y / N**

Is this/are these sinks routinely used by a floater? **Y / N**

How far from the change mat is the sink where staff wash their hands?

within one metre ie. reachable arms length

one step away

more than one step away

Does the sink where staff wash their hands have hot water ? **Y / N**

Does the sink where staff wash their hands have warm mixed water ? **Y / N**

What soap is available for staff to wash their hands?

Liquid soap	***before trial***	***Liquid soap***
Bar soap		***Bar soap***
Other		***Other*** .....

What is available for staff to dry their hands?

Paper towel	***before trial***	***Paper***
Shared cloth towel		***Shared Cloth***
Individual cloth towel		***Individual towel***
Hot air dryer		***Hot air***

How many sinks where **toddlers** can reach **(without help)** to wash hands? .....

Are these reachable sinks also used by children from another room? **Y / N**

Does the sink where toddlers wash their hands have warm water ? **Y / N**

What soap is available for toddlers to wash their hands?

Liquid soap	***before trial***	***Liquid soap***
Bar soap		***Bar soap***
Other		***Other*** .....

What is available for toddlers to dry their hands?

Paper towel	***before trial***	***Paper***
Shared cloth towel		***Shared Cloth***